

# **Clinical Laboratory Assessment & Improvement Strategy**

## **Final Report**

### **April 7, 2008**

# Scope of Responsibility

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- *This report has been prepared by **Navigant Consulting, Inc. (NCI)**, solely for the use and benefit of **California Prison Health Care Receivership Corporation (CPR)** hereinafter referred to as (Client), located in **Sacramento California**, for consulting services (Services) pursuant to an agreement between **California Prison Health Care Receivership Corporation** and **NCI** dated October 5, 2007. The scope, process and timetable of NCI's work are identified in that agreement.*
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- *The information, opinions and recommendations contained in this report have significance only within the context of the entire report. No parts of this report may be used or relied upon outside that context.*

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## Section I – Introduction

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- Navigant Consulting Inc. Team
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- Meetings and Interviews
- Executive Summary
  - Immediate Recommendations
  - Issues
  - Corrective Action
  - Cost

# Engagement Objectives

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- NCI was asked to evaluate California Department of Corrections and Rehabilitation (CDCR) laboratory facilities and services with the following objectives:
  - Conduct an operational and risk assessment of the existing laboratory network in which facilities will be evaluated individually in terms of their overall operational infrastructure, and collectively as a network;
  - Render recommendations on the strategic restructuring of the laboratory program in accordance with the mission of the CDCR (and the CDCR's planned enhancements in healthcare, including an overhaul of information systems); and
  - Create a plan with clear priorities and accountabilities for implementing the project's recommended improvement interventions and for monitoring progress going forward.

# Scope of Work

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- Specifically NCI agreed to:
  - Conduct an operational and risk assessment of the current state of the laboratory network.
  - Evaluate the feasibility of in-house and/or contracted (purchased) laboratory services.
  - Conduct an assessment of the existing Point of Care Testing (POCT) program (including STAT services available).
  - Evaluate the feasibility of centralized or regionalized laboratory services.
  - Evaluate existing and needed information systems.
  - Assist in creating a vision for a future, optimized operating model.
  - Determine the type and level of POCT and STAT services necessary to support the clinical needs of patients and physicians.
  - Determine the best strategic contracting/partnership relative to commercial laboratories.
  - Determine if centralization of laboratory services best fits CDCR's ideal model.

# Outcomes

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## **Milestone I**

- Establish CPR Executive Steering Committee to participate in engagement oversight.
- Develop detailed time table for project completion and key deliverables.
- Begin CDCR facility on-site visits and interviews.

## **Milestone II**

- Convene second meeting with Executive Steering Committee.
- Complete site visits and stakeholder interviews.
- Present preliminary assessment findings with focus on areas of priority.

## **Milestone III**

- Convene third meeting with Executive Steering Committee.
- Present draft of initial models.
- Complete data collection efforts and data evaluation.

## **Milestone IV**

- Convene final meeting with Executive Steering Committee.
- Present final laboratory operational models, including logistics and cost.

## Navigant Consulting Inc. Team

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- Maria Torres, CHC, MBA, MT (ASCP), SBB Consultant
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# CPR Steering Committee

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- Allen Freuh, M.D.
- Justin V. Graham, MD., M.S., Chief Medical Information Officer
- Nadim Khoury, M.D.
- Terry Hill, M.D., Chief Medical Officer
- John Hummel, Chief Information Officer
- Stan Ketchum, PMP, Project Manager
- Richard Kirkland, Director, Plata Support Division
- Glen Moy, Director of Health Information Integration
- Yulanda Mynhier, Assistant Deputy Director
- William Wilson, Central Regional Administrator

## Meetings and Interviews

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- To develop a robust understanding of the issues, NCI met with CPR representatives, Correctional Facility health care providers and administrators, Laboratory Vendors and Reference Laboratory Service Providers, as well as Sacramento Administrative stakeholders. (Exhibit I)
- NCI used a multidisciplinary Steering Committee to review the deficiencies and recommendations for development of strategic models, comprehensiveness, and ability to execute. NCI and the CPR Steering Committee met four separate times.
- NCI interviewed Correctional Facility representatives from other states including Texas, New York, Nevada, and Florida to identify best laboratory practices of laboratory service models in the prison environment (Exhibit IV)

# Executive Summary – Immediate Recommendations

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- The existing clinical laboratory services fail to provide the necessary service requirements to guarantee safe and adequate quality healthcare to inmates at the CDCR facilities.
  - 48% of the CDCR facilities are concerned with STAT turn around time; 94% perform Point of Care Testing without the proper medical oversight; and 21% reported multiple incidents of questionable quality of test results. (Exhibit XVI)
- CDCR will be required to implement immediate improvements to minimize risk, and concurrently begin planning a long-term corrective action plan to overhaul existing laboratory systems and create a safe and sustainable future operational model.
- *In light of the findings presented in this report;*
  - CDCR will need to establish adequate governance and oversight of laboratory services.
  - CDCR will need to strategically cease laboratory testing at facilities without licensed Acute Hospital Beds, as deemed prudent based on Key Improvement Plan Activities).
  - CDCR will implement adequate POCT at all facilities.
  - CDCR will resolve the reference laboratory vendor relationship, cost, quality, and STAT service.
  - CDCR will initiate a formal deployment of additional ‘Key Improvement Activities’ contained in this report.
  - CDCR will begin planning a long-term laboratory operational model based on improvements and various models identified in this report.

## Executive Summary – Issues

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- Physician performance is severely hindered by the inability of laboratories to provide basic laboratory information, which is required for adequate patient management. This in turn is leading to waste, unnecessary testing, and treatment delays.
- The overall laboratory services enterprise operates in a vacuum without the required level of leadership and management; it lacks accountability and oversight.
- The overall laboratory enterprise is in need of radical change and a comprehensive overhaul is due - several laboratories operating *within* CDCR facilities will need to be closed, while adequate provisions will need to be implemented to support access to STAT laboratory services.
- The infrastructure of laboratories operating within CDCR facilities is sub-standard and unsustainable in its current state.
- The reference laboratory services purchased from commercial providers is driven by 'low cost' with little emphasis given to aligning quality and service.
- The relationship with commercial laboratories lacks any level of accountability, which is resulting in substandard services and broken contractual obligations. (Exhibit VI)
- The Medical Directorship required to comply with State and Federal Regulations is sorely missing.

## Executive Summary – Issues

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- Two facilities operating in-house laboratories have discontinued testing since December 2007 (CMF\* and CCI) due in part to infrastructure, inadequate medical directorship, and regulatory concerns; other facilities may soon follow suit unless preventive steps and/or corrective action are taken.
- The training of personnel, competency validation, and required quality control monitoring are inadequate and in some cases non-existent.
- The operational workflow for blood collection, testing and reporting of laboratory results is inefficient and plagued with burdensome paper work.
  - Test results are frequently not available in the chart for physicians to manage their patients and render the necessary care; unnecessary test re-orders are common.
- Laboratories lack the necessary centralized management structure; as well as appropriate policies and procedures, test menus and priorities, information systems, and proper supervision of processes and personnel.
- The organizational structure is cumbersome and personnel classification is ineffective to attract the required level of personnel. Recruitment and retention of qualified laboratory personnel is hindered by poor working conditions, remote facility locations, and low pay.

*\* At the end of February 2008, CMF passed a regulatory inspection conducted by the State's Field Services inspectors, following CMF's diligent corrective action implementation.*

## Executive Summary – Issues

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- The rate of pay for Clinical Laboratory Scientists is 27% under the market rate and 50% of phlebotomists are registry personnel.
- Laboratory facilities and infrastructure are inadequate and outdated in almost every aspect and cannot support in-house laboratory operation improvements, unless the status quo is desired; their chances of modernization to create an optimal and sustainable environment are slim.
- The laboratory enterprise lacks the necessary Laboratory Information System (LIS) to provide universal access to laboratory orders and test results. The limited stand-alone LIS capabilities that exist at six laboratory facilities are inadequate to achieve the required improvements.
- Laboratories have incorporated sub-standard, yet necessary, manual specimen collection schedules and patient logs, handwritten test requisitions, and manual entry of test results, among other processes.
- Test results from commercial laboratories are, at times, of questionable accuracy, delays in turnaround time are not uncommon, and access to timely STAT testing support is consistently unacceptable. (Exhibit VII)
- Reference laboratory billing is outside standard laboratory market billing practices. (Exhibit VIII)
- The current procurement of laboratory supplies, driven by Sacramento, is cumbersome, ineffective, and frequently wasteful.

## Executive Summary – Corrective Action

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- The laboratory enterprise requires a well thought-out improvement plan that will first include a 'Key Improvement Phase' to create the basic and fundamental infrastructure that will precede future strategy.
- The future state of clinical laboratory services for CDCR will include quality and safety guarantees through the creation of an 'Integrated Laboratory System' constituting key attributes, such as:
  - External (independent) oversight of the clinical laboratory enterprise.
  - Internal, multidisciplinary, centralized governance; medical directorship, and laboratory management.
  - A comprehensive, enterprise-wide, quality management program encompassing all areas and aspects of laboratory services, operations, and infrastructure.
  - Appropriate space and state-of-the-art equipment.
  - Robust, enterprise-wide laboratory information systems.
- The overall laboratory improvement plan will be aligned with CDCR-wide health care improvements.
  - Key improvements, deployed concurrently, will occur over a period of 3 - 18 months with the bulk of the benefits realized by month 12; a full improvement strategy, including a new strategic model, may take up to 48 months.

## Executive Summary – Cost

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- NCI estimates the current laboratory services cost CDCR approximately \$30M/Yr. Costs will increase to approximately \$35M/Yr over the next five years.
- Long-term improvements are estimated to require between \$2.4M - \$6.7M in one-time capital expenses depending on the future operating model.
- Operational costs of improved laboratory services will range from \$33M/Yr - \$37M/Yr over the next five years depending on the strategy.
- NCI evaluated various future laboratory operational models presented in this report. The ideal long-term model is for CDCR to “establish a single off-site core laboratory supported by advanced POCT and robust local STAT services with contracted local hospitals and a reference laboratory partner.” This model guarantees high-quality and yields five-year cumulative savings of approximately \$5M.
- In NCI's experience this model has the potential to additionally reduce operating costs by 10-15% over five years.
- ***In summary, it is NCI's opinion that maintaining the status quo in laboratory operations is unsafe and prone to trigger adverse patient outcomes. In addition, current laboratory operations are unsustainable and unfit to support the health care improvement mission of CDCR. Radical changes and improvements must be made.***

## Section II – Operations Assessment

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- Baseline Assessment
  - Evaluation Methods
  - Background Information
  - Laboratory Operations
  - Laboratory Information Systems (matches headers)
  - Laboratory Facilities (matches headers)
  - Capacity
  - Technology
  - Test Menus
  - Reference Laboratory Services
  - Staffing and Job Descriptions

# Baseline Assessment

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- NCI completed an evaluation of CDCR laboratory services to understand their operations. The scope of this review consisted of the following areas:
  - Overall infrastructure with emphasis on Clinical Laboratory Operations, including:
    - Management and oversight
    - Test utilization and cost
    - Information Systems
    - Personnel levels and staff mix
    - Work flow
    - Reference laboratory services
    - Facility and space
    - Equipment and testing platforms
    - Quality management systems and compliance; directorship
    - Purchasing and procurement
    - Test menus and turnaround times (STAT and routine)
    - Overall pre-analytical, analytical, and post analytical processes

# Baseline Assessment – Evaluation Methods

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- On-site visits to eight (8) correctional facilities; 25 telephone interviews with Chief Medical Officers, Healthcare Managers, Physicians, and laboratory personnel.
- Formal meetings with CPR Steering Committee representatives.
- Meetings with facility planners and architects.
- Direct observation of on-site operations, including POCT.
- On-site visit and interviews with Foundation Laboratory - the main commercial laboratory servicing CDCR.
- Interviews with Quest Reference Laboratory – the secondary commercial laboratory servicing CDCR.
- Interviews with key laboratory equipment vendors and manufacturers.
- Data evaluation from Sacramento government offices relative to staffing and contracts.
- Evaluation of technological resources, including information systems and equipment.
- Assessment of service levels and stakeholder satisfaction (excluding inmates).
- Research of best practice models of correctional facilities in New York, Texas, Florida, and Nevada. (Exhibit IV)
- Research of logistical courier requirements and resource availability in the state of CA to support recommended models. (Exhibit XV)
- Development of financial and various operational models.

## Baseline Assessment – Background Information

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- The CDCR laboratory network supports 33 adult prison facilities that house over 160,000 inmates; each facility is overpopulated.
- Three facilities have a total of 135 licensed acute care hospital beds; 17 facilities have a total of 363 Correctional Treatment Center (CTC) licensed beds.
- The utilization of laboratory services varies with the type of medical care provided at each facility. For example, reception centers require greater phlebotomy and have a higher utilization of tests; there are ten reception centers in the system.
- Facilities with licensed Acute Care Hospital and Correctional Treatment Center licensed beds have a higher utilization of routine and STAT testing.
- Eleven (11) prisons have capabilities to operate in-house laboratories. Nine of these facilities perform basic laboratory testing in chemistry, hematology, coagulation, and urinalysis.
- The laboratory network operates with approximately 105.5 FTEs considered State employees; additionally there are 63.6 agency phlebotomists.
- NCI estimates CDCR spends in excess of \$30M/Yr in laboratory services, including in-house, send out, and other costs. The poor quality and lack of accurate data throughout the enterprise made it impossible to establish an exact cost.
- NCI estimates the cost of laboratory services performed under the control of CDCR is approximately \$15.8M/Yr (\$13.4M salaries including agency and \$2.4M in materials and supplies).
- NCI estimates CDCR spends \$15.1M in reference laboratory services.

# Baseline Assessment – Laboratory Operations

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- The CDCR laboratory network operates in silos and lacks proper Medical Directorship, management, and a basic solid foundation to provide safe and adequate quality services.
- The pre-analytical process is plagued with inefficiency; it lacks policies and procedures to ensure specimen quality and integrity.
- The movement of inmates from yards to a central phlebotomy station, at some sites, is inefficient and burdens the system.
- CDCR contracts with three independent Medical Directors (Pathologists) to oversee laboratory services and provide the required oversight; their involvement is minimum and excludes POCT.
- The POCT program functions without medical directorship oversight; testing is performed by untrained personnel; the program lacks quality control programs, personnel competency validation, and standardization.
- The enterprise lacks the necessary job descriptions for Laboratory Medical Directors who oversee existing in-house laboratory operations. In addition, the required staff competency validation is either limited, substandard, or does not exist at several facilities.

## Baseline Assessment – Laboratory Operations

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- The current management of laboratory services is completely fragmented without central guidance, oversight, and accountability. Local sites in-turn operate in a vacuum; local laboratory management and supervision is inadequate.
- The ability of Clinical Laboratory Scientists to provide sound quality laboratory services is questionable; training and competency validation is unavailable in some instances; the infrastructure of each laboratory is obsolete; laboratory equipment is outdated; information systems are stand-alone and offer limited capabilities.
- Laboratory scientists are used inefficiently and must perform an overwhelming amount of non-technical duties.
- Laboratory services lack the basic laboratory management and administrative reports.
- The weak/obsolete operating environment at most facilities presents an impediment to improving work flow or streamlining laboratory functions; as result all phases of laboratory testing (pre-analytical, analytical, and post-analytical) are affected.

# Baseline Assessment – Laboratory Information Systems

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- The enterprise lacks an integrated Laboratory Information System, which results in major inefficiencies and waste while overwhelming the entire health care continuum across facilities, while jeopardizing the quality of care given to inmates. (Exhibit III)
  - Based on interviews, NCI estimates at least 20% of the laboratory orders are repeated because physicians lack access to test results when caring for patients.
- The existing information system capabilities are either limited, non existing, weak and/or obsolete. Electronic access to test results from commercial laboratories is available in some instances, but its use is marginal in most cases.
- A large portion of records are kept in manual logs, in lab paper files and paper charts.
- Record retention methods are not standardized, lack the necessary controls, and involve extensive manual resources – a process does not exist for long term storage and integration of records.
- The information system capabilities offered by Quest Reference Laboratories (Care 360) and Foundation Laboratories (Skynet) provide some (browser-based) access to test results. However, only a limited number of CDCR laboratories and clinics take advantage of these systems due to connectivity issues, lack of training, lack of hardware, and lack of a sense of urgency and accountability for a full deployment of system features.

# Baseline Assessment – Laboratory Information Systems

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- Existing laboratory information system (at facilities performing laboratory testing) can not support the current or future needs of CDCR.
  - Electronic order entry is only available within the laboratory; therefore, manual requisitions are required to order laboratory tests which increases labor cost and the chance for errors.
  - Interface to laboratory instrumentation is limited and of a ‘stand alone’ nature; therefore, test results are entered manually, which increases the chance for reporting errors.
  - Laboratory reports are not consolidated; physicians get results from the same day in multiple pieces of paper; medical records is further overwhelmed with paperwork.
  - The systems are not capable of producing special reports for trending results across time or monitoring therapies based on laboratory results.
- Existing laboratory information system capabilities, internal and externally provided by commercial laboratories, do not meet the required order entry, analytical, and result reporting needs of the CDCR health care delivery system.
- The CDCR, clinic-based POCT program, lacks any type of electronic access to test results.

## Baseline Assessment – Laboratory Information Systems

- NCI identified at least six laboratory information systems, which operate in a stand-alone fashion and can not support the modernization of the overall CDCR health care infrastructure in their current state. Laboratory facilities independently acquire information systems, which are frequently aligned with laboratory equipment arrangements.

LIS Key Features	Skylab	Fletcher-Flora	Genesis	Med-Com	Gem	CSS
Electronic Order entry	Y	Y	Y	Y	Y	Y
Track complete sample-results data	Y	Y	Y	Y	Y	Y
Control and record completed test data (Including QC)	N	N	N	N	N	N
Provide clinic base result information	N	N	N	N	N	N
Accumulate results to historical data base	Y	Y	Y	Y	Y	Y
Bar code labels for sample tubes	Y/N	N	N	N	N	Y
Interface to Laboratory equipment	Y	Y	N	N	N	Y
Direct interface to reference laboratory	N	N	N	N	N	N
Ability to create special reports for trending results across time	N	N	N	N	N	Y
monitoring therapies based on laboratory results	N	N	N	N	N	N

# Baseline Assessment – Laboratory Facilities

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- The existent facility and space dedicated to laboratory services do not meet the necessary standard of care and regulatory requirements for the most part.
- The existing space configuration is obsolete at all facilities operating in-house laboratories; space is limited at all facilities, except CMF.
- The CDCR facilities offering blood draw services perform laboratory functions in inadequate space, which presents HIPAA implications and unsafe working conditions.
  - Space within the laboratory dedicated to blood draw functions is too small, outdated, and not conducive to protecting patient privacy and confidentiality.
  - Blood draws are frequently performed in hallways or space shared with other functions.
- All laboratories, except CMF, lack the necessary space for specimen collection, processing, and testing – available space is outdated and in need of significant remodeling.
  - Workbenches are too small and cluttered with instrumentation and paper work.
  - Stand-alone instrument layout is inefficient due to space constraints.
  - Record storage space is virtually non-existent; most records are stored in paper boxes located underneath workbenches creating fire hazards.

## Baseline Assessment – Laboratory Facilities

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- All laboratory facilities are in need of significant facility overhaul and modernization, but in addition a comprehensive facility planning is required, particularly as CDCR is planning a comprehensive facility improvements and new sites, e.g., 5,000-hospital bed initiatives.
- Furthermore, the acceptance and implementation of the laboratory corrective action strategy outlined throughout this report will have significant facility-related implications and should be carefully considered early in the overall CDCR/CPR planning discussions.

## Baseline Assessment – Capacity

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- The CDCR laboratory's network overall technological infrastructure is outdated and obsolete in most areas.
  - In-house laboratory operations (11 facilities) are unsustainable in their current state relative to staffing challenges, obsolete space, outdated equipment and instruments, lack of information systems, inadequate medical directorship arrangements, outdated work flow and weak operational systems, inadequate procurement of reagents and supplies, and lack of management and oversight among several other factors.
  - Phlebotomy and pre-analytical laboratory operations, although sustainable, are inadequate and unsafe, while consuming excessive resources; the same presents significant gaps in patient privacy and confidentiality.
- The Laboratory Enterprise supports approximately 2.3 million annual tests; approximately 578,000 of these tests are performed at CDCR-based laboratories; the rest are outsourced to commercial laboratories.
  - *NCI was unable to produce an exact calculation of test volumes due to [the lack of] and/or poor quality of data available.*

# Baseline Assessment – Capacity

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- CDCR normally operates in-house clinical laboratories at eleven (11) facilities, including: CIM, CMC, CMF, COR, KVSP, NKSP, PVSP, SAFT, SVSP, WSP, and CCI. Presently, there are ten (10) facilities with active laboratories.
  - *CCI ceased laboratory testing as result of NCI's initial findings. Testing has not been reinstated as of the publication of this report.*
  - *CMF voluntarily ceased laboratory testing for several weeks to address regulatory concerns, but reinstated on-site testing by the end of February 2008, after implementing the required corrective action. CMF laboratory was surveyed by the State of California and it has been deemed in compliance with minimum State Licensure requirements to perform a limited test menu.*
- Despite recent improvements at CMF and the local efforts of facility staff to provide good quality 'in-house' laboratory services, CDCR-based laboratories clearly face enormous challenges with their current operating infrastructure and overall environment.
- CDCR-based laboratories, in their current state, are not positioned to operate safely, efficiently, or cost effectively; while the same consume (and waste) significant (and costly) resources to be able to maintain the status quo.
- The state of the current laboratory infrastructure significantly hinders any opportunity to increase capacity, streamline operations, improve work flow, or implement sustainable improvements, overall.
- The CDCR laboratory services will require overhaul and a new strategy before it can achieve significant improvements.

## Baseline Assessment – Technology

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- CDCR-based laboratories require only a limited number of instruments based on their limited test menus; yet the system lacks standardization. Each facility makes independent decisions when dealing with vendors, selecting methodology, and establishing testing platforms, test menus and reference ranges.
- Laboratory analyzers are outdated in some instances and facilities obtain brand new instruments without conducting the necessary due diligence.
- All facilities lack back up instruments; laboratory cease operations when instruments break down.
  - Frequently it may take several days before instruments are repaired, thus forcing the use of reference laboratory while increasing cost, affecting turnaround time of results, and overwhelming the already antiquated operational systems.
- The procurement of reagents, supplies, and proficiency testing is subjected to unnecessary scrutiny. For instance, RFPs for proficiency testing materials and analyzer-specific materials (available only through one vendor nationally) are required each year.

## Baseline Assessment – Technology

- Eleven existing in-house laboratories currently have a mix of at least three types of chemistry analyzers; four different types of hematology analyzers, and multiple miscellaneous analyzers.
- Some facilities have acquired new equipment, which has not been implemented for various reasons; other facilities own equipment which has been displaced for years, yet remains located within the laboratory space.
- At the present time there are facilities, such as San Quentin in the midst of evaluating laboratory equipment.

LABORATORY EQUIPMENT					
Number of Analyzers	Siemens	Coulter	Abbott	J & J	Other
Chemistry	9			3	1
Hematology	2	3	4		7
Urinalysis					4

**CDCR should cease all laboratory equipment acquisition activities until such time that a formal plan is established with the proper monitors, standardization, and accountability in place.**

## Baseline Assessment – Test Menus

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- CDCR-based laboratories provide basic clinical laboratory services, including:
  - Hematology - cell counts, sedimentation rates, and urinalysis, among other simple tests.
  - Chemistry – basic and comprehensive metabolic panels, thyroid screening, therapeutic drug monitoring, prostate screening, glycohemoglobin, among other simple procedures.
  - Coagulation and serology – PT, INR, PTT, RPR among other simple serological tests.
    - Although the data available for NCI's review seems unreliable, NCI considers 85% - 90% of all CDCR testing are basic tests, while the remaining volume is more esoteric and is referred to commercial laboratories.
- CDCR lacks any type of test menu standardization – available test menus at each facility are driven by 'availability of resources' rather than patient care needs and physician expectations.
- CDCR lacks any standardization of test priorities, reference ranges, and STAT test menus.
- The enterprise lacks the necessary control mechanisms to monitor utilization of services, but at the same time there are facilities actively planning to introduce new test offerings (in-house).

**CDCR should hold the introduction of new test methodologies or procedures until such time that a strategy is coordinated and includes proper monitors, standardization, and accountability in place.**

# Baseline Assessment – Reference Laboratory Services

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- Reference laboratories perform approximately 1.7 million tests per year for CDCR inmates at a yearly cost of \$15,096,241.
  - Approximately 1,141,408 tests are referred to Foundation Laboratories at an annual cost of \$10,982,346.
  - Approximately 476,656 tests are referred to Quest Diagnostics at a cost of \$4,095,924.
  - Some CDCR facilities use local hospital/other providers, outside the commercial laboratory arrangement.
- Over 70% of all laboratory tests necessary to manage CDCR inmates are performed through contractual agreements with two main (separate) reference laboratories.
  - Foundation Laboratory supports 22 CDCR facilities.
  - Quest Diagnostics supports 11 CDCR facilities.
- State Health laboratories perform approximately 51,000 tests per year at a cost of \$17,572 - *The relationship with these laboratories is valued by the physicians.*
- The current contractual arrangement with the two reference laboratories requires them to provide routine and STAT services for their corresponding CDCR facilities, including anatomic pathology.
- NCI interviews with CDCR personnel identified some facilities refer some of the services to other providers (e.g. local hospitals and pathology groups), outside the established reference laboratory arrangement with the main vendors.

## Baseline Assessment – Reference Laboratory Services

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- Reference laboratory providers frequently fail to meet the needs and service expectations of the facilities they serve. (Exhibit VII)
- Most physicians (interviewed) do not trust the accuracy of results from Foundation Laboratory and have experienced significant discrepancies with their test results.
- CDCR facilities consistently experience issues with the limited or non-existent availability of STAT services – **contractually required** – from both commercial laboratories. (Exhibit VI)
- NCI identified logistical issues with couriers, lack of reference laboratory agreements with local hospitals, and CDCR staff unfamiliar with proper way to access STAT laboratory services, all contribute to this situation.
- Reference Laboratory billing practices, although on par with CDRC's agreement, are not according to current (market) standard billing practices.
  - Multiple fee schedules exist.
  - Tests are unbundled, then billed.
  - The cost of STAT testing and tests not performed at the reference laboratory headquarters is passed on to CDRC and exceed market prices. (Exhibit VIII)
  - CDCR pays for services, which are typically 'non-billable' such as: test calculations and tests performed on unsatisfactory specimens, which require re-collection of the specimen.

## Baseline Assessment – Staffing and Job Descriptions

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- CDCR lacks the required job descriptions for Laboratory Medical Directors.
- CDCR currently has three categories of Clinical Laboratory Scientists, including: Clinical Laboratory Technologists; Senior Clinical Laboratory Technologists, and Supervising Laboratory Technologists.
- The nomenclature and content of these job descriptions is outdated and needs to reflect current state licensure requirements.
- NCI recommends two categories of Laboratory Technologists: (1) Clinical Laboratory Scientists, and (2) Senior Clinical Laboratory Scientists. (Exhibit X, XI)
- The Senior Clinical Laboratory Scientist will be the equivalent of the current Supervising Laboratory Technologists. In addition, for the current level of testing there should be no other categories of licensed laboratory personnel. The two proposed categories will meet the needs for the level of testing performed at prisons with in-house laboratories.
- CDCR utilizes two different categories of Laboratory Assistants (1) Laboratory Assistant I and (2) Senior Laboratory Assistant. NCI recommends that there will only be one category of Laboratory Assistant and the job descriptions will be updated to reflect the current State Licensure Requirements for a Certified Phlebotomist Technician I. This level of personnel can perform all the duties of a laboratory assistant and venipunctures, except arterial punctures. (Exhibit IX)

## Section III – Corrective Action

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- Discussion
- Key Improvement Activity Deployment Plan
- Integrated Laboratory Service Delivery Model
- Long-term Operational Model Deployment Plan
- Long-term Operational Model Expectations
- Long-term Operational Model Implementation Assumptions

## Corrective Action – Discussion

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- The current state of laboratory services at CDCR fails to provide the required level of quality and service – bringing existing in-house laboratories up par will be costly, challenging, and unnecessary in most instances while not guaranteeing successful and sustainable outcomes. NCI was unable to identify any prison-based laboratory model currently operating in-house clinical laboratories. (Exhibit IV)
- CDCR should consider limiting the number of CDCR-based (in-house) laboratories to facilities required by regulatory mandate. There are only three prisons that meet this criteria: Corcoran, California Men's Colony and California Medical Facility, mainly because they operate Licensed Acute Hospital beds. (Exhibit XII)
- Consequently, CDCR should plan to cease in-house laboratory testing at the other eight facilities after careful planning and execution of a robust transition plan.
- CDCR should (concurrently) plan to establish a robust POCT program at all facilities based on their required level of service and utilize existing technical staff to support these efforts.
- CDCR should plan an urgent strategy to resolve STAT-related service and quality concerns and introduce the necessary accountability involving reference laboratories.

## Corrective Action – Discussion

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- CDCR needs to prioritize the introduction of formal external oversight of laboratory services, and the formation of an internal multidisciplinary governance body to drive all strategic changes.
- Last, CDCR needs to move ahead toward establishing a comprehensive, long-term laboratory strategy, aligned with the overall CDCR health care mission and vision, and that guarantees long-term quality, cost effectiveness, and sustainability of laboratory operations.

**The following part of this section will focus on the improvement plan beginning with ‘Key Improvement Factors’; followed by the creation of an ‘Integrated Laboratory Service Model’; and finally a ‘Long-Term Strategy’.**

## Corrective Action – Phase I - Key Improvement Activity Deployment Plan

* Key Improvement Phase - Initiatives	Time Line
Develop RFP and select Reference Lab Partner	April - June 2008
Formulate Independent Oversight plan; draft work plan	April - May 2008
Establish Interim System Governance and CDCR operational transition team	April - May 2009
Develop an RFP for Laboratory Medical Directorship; implement directorship accordingly	April - July 2008
Revamp STAT lab services delivery	April - June 2008
Standardize POCT - Level I	May - Aug. 2008
Establish enhanced POCT - Level II	May - Oct. 2008
Perform system wide regulatory compliance assessment and implement remedial actions	April - May 2008
Develop interim IT plan for POCT and reference laboratories	May 08 - May 09
Dissolve non-essential laboratory facilities	Sept. - Nov. 2008
Establish utilization monitors	May 08 - May 09
Establish laboratory space requirements based level of service	May 08 - ongoing
Establish communication plan for all stakeholders	April - May 2008
Validate the overall impact of completed Key Improvement initiatives and formulate transition plan to a desired long-term model	May 09 - Nov. 09

*\* Each improvement initiative will require an in-depth action plan, including improvement monitoring criteria.*

*Dates may vary based on start date, resources available to carry out initiatives, and overall buy-in.*

**During the 'Key Improvement' phase CDCR will plan the strategic closure of non-essential in-house laboratories, including a sound transition**

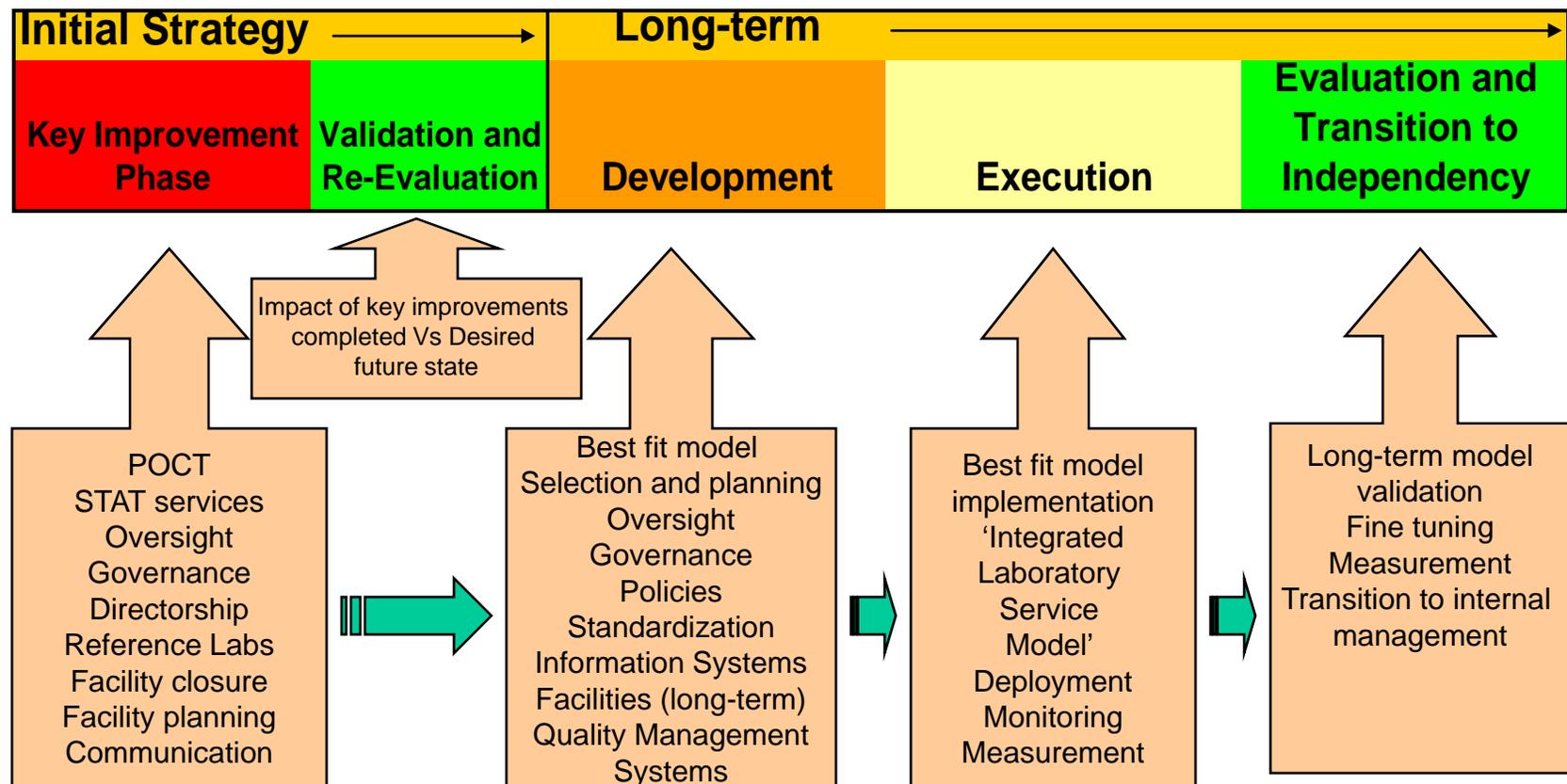
## Corrective Action – Integrated Laboratory Services Model

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- CDCR laboratory long-term improvements will begin an ‘Integrated Laboratory Services’ model.
- The integrated system will be guided by a Governance body represented by a “Laboratory Physician Council” made up of pathologists, physician providers, other clinicians and laboratory management.
- The function of the Laboratory Physician Council will be to establish a standardized level of service for the system and each site, which will include test menu, test priority, test utilization guidelines and overall service requirements for in house testing, POCT and tests referred to a reference laboratory.
- Management of laboratory services will be centralized and its primary function will be to implement a Quality Management System that will provide:
  - Administrative and operational policies and procedures.
  - Personnel selection, training and development.
  - Independent, criteria-based selection and purchase of all laboratory equipment, supplies and services.
  - Standards of performance to monitor and ensure integrity and effectiveness of all phases of laboratory testing and services.
  - Centralized process for evaluating, monitoring and complying with regulatory requirements.

# Corrective Action – Long-term Operational Model Deployment Plan

- The overall strategic improvement of laboratory operations at CDCR will involve several stages beginning with Key Improvements of basic operations, leading to a desired 'Future State' of laboratory services in a sustainable long-term model.



# Corrective Action – Long-term Operational Model Expectations

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- CDRC will implement a long-term operational model that fulfills the clinical, operational, and administrative goals of CDCR facilities, CPR, and its stakeholders, including:
  - **CDCR and CPR**
    - High quality of healthcare delivery to CDCR inmates.
    - Standardization of laboratory services throughout the system.
    - Electronic access to laboratory orders and results and integration with the EMR.
    - Effective test utilization to positively impact clinical outcomes.
    - Experienced laboratory system leadership and management.
    - Proficient laboratory personnel.
  - **Physician providers:**
    - Accurate laboratory test results on time to effectively monitor, diagnose and treat
    - Timely access to STAT laboratory services
    - Test results available in the chart and electronically at the POCT and system-wide transparency
    - Standardized test menu, test priorities, reference ranges
  - **CDCR laboratory personnel:**
    - Medical Directorship to oversee the implementation of a Quality Management System
    - Education, training, coaching, and accountability
    - State of the art equipment
    - Adequate and safe space
    - Laboratory information systems

# Corrective Action – Long-term Operational Model Expectations

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- The preferred models will balance Cost Effectiveness and Best Demonstrated Practices (BDP) in the industry.
- POCT services will be available in three levels of testing driven by specific needs of each prison, including:
  - POCT Level I: Basic, CLIA-waived tests such as glucose and urine dipstick.
  - POCT Level II: Enhanced test menu of basic chemistry and hematology (15 tests of CLIA moderate complexity).
  - POCT Level III: Expanded test menu, which may include type and cross-match, but limited to three facilities retaining an in-house laboratory. Testing services may include a rapid response lab and/or enhanced POCT.

*Note: Basic POCT will be available at all facilities.*

## **Key Point:**

- Any operational service expectations must include:
  - A Laboratory Information System that provides system-wide access to orders and results and is fully integrated to the patients electronic medical record.
  - Sound partnerships with a reference laboratory providers that includes full accountability for service levels. This partnership may include logistic support for courier services and STAT lab contracts.
  - The creation of robust infrastructure including: clinical, operational, regulatory, and administrative.

## Corrective Action – Long-term Operational Model Expectations

- POCT will play a critical role in the implementation of any preferred model. The following tentative menu will be used as a starting point by the multidisciplinary to define the required test menu and level of services for each facility.

Rapid Response Laboratory	Enhanced POCT
Basic Metabolic Panel	Creatinine
Comprehensive Metabolic Panel	BUN
Electrolytes	Glucose
Therapeutic Drugs	Ionized Calcium
Hemoglobin A-1-C	Sodium
Pregnancy testing	Potassium
Urinalysis	Total CO2
Drugs of Abuse urine screen	Troponin I
Rapid plasma reagin	PT INR
CBC with Differential	Blood Gases
PT INR and PTT	Hematocrit and Hemoglobin

## Corrective Action – Long-term Model Implementation Assumptions

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- The development of the selected long-term model will include an independent relationship between CDCR/CPR and key vendors.
- The procurement and purchasing of goods and services will be based on quality expectations and cost effectiveness, not on cost alone.
- The fine-tuning and implementation of a long-term model and overall system standardization will include significant involvement from a CDCR Governance body.
- The proposed timeline required for the implementation of any of the three models will take three to four years for completion – Year one will mainly focus on Key Improvement activities to create a basic, yet robust infrastructure that provides access to timely and safe laboratory services.
- External oversight and management of laboratory services will be provided by an entity with expertise in laboratory medicine with the proper level of accountability and authority to drive change.
- The external oversight entity will be allowed to conduct the following functions with limited bureaucratic red tape:
  - Establish CDCR laboratory governance and immediately begin contracting with a qualified pathology group, under central agreement with CDCR/CPR to begin a quality overhaul of all laboratory services.

## Corrective Action – Long-term Model Implementation Assumptions

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- Complete request for proposal for reference laboratory service to ensure continuation of services - *The current reference laboratory agreements expire on June 30, 2008.*
- Revamp access to STAT laboratory services concurrent with the reference laboratory proposal.
  - Many prisons lack access to STAT laboratory services, which jeopardizes care.
  - Many inmates are sent unnecessarily to a local hospital costing thousands of dollars per event, yet an inexpensive lab test could have prevented the hospital visit.
- Standardize basic POCT including glucose monitoring by the second quarter of 2008.
  - Several prisons are currently negotiating independently with different vendors to switch glucose monitor devices for their site. A system-wide approach with a thorough quality and cost evaluation will ensure that the standard of care is met for POCT.
- Perform a system-wide regulatory compliance assessment and implement remedial actions.
- Drive space planning related efforts and align the same with CDCR Master Facility Planning.

## Corrective Action – Long-term Model Implementation Assumptions

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- CDCR/CPR will invest in the acquisition and implementation of the required Laboratory Information Systems that support the connectivity of instruments and multiple information systems; provides reference laboratory interfacing; as well as all required system to system connections to secure seamless exchange and access to laboratory data, including POCT.
- The established Governance body will drive the enactment and standardization of service guarantees to ensure that all laboratory results are available in a timely fashion, including:
  - Routine laboratory tests results available within 24 hours or next day from the time of order.
  - STAT services will be available to all sites 24 hours a day 7-days a week and will be provided through a network of: on-site rapid response labs; enhanced POCT; arrangements with a local laboratory providers and local reference laboratory hubs.
  - STAT results will be available within 4 hours of the test order. All critical values will be called immediately upon result verification to the appropriate care giver.
- The established Governance body will drive the enactment standardized policies and procedures, including test menus and testing methodologies throughout the enterprise and for all laboratory service levels.

## Section IV – Future State

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- Operational Models Considered
- Preferred Operational Models
  - Service Delivery
  - Performance Criteria
  - Costs, Current and Five-Year
  - Savings Projections
- Laboratory Model A Definition
  - Pros and Cons
  - Logistics
  - Costs
- Laboratory Model B Definition
  - Pros and Cons
  - Logistics
  - Costs
- Laboratory Model C Definition
  - Pros and Cons
  - Logistics
  - Costs

# Future State – Operational Models Considered

- NCI evaluated six different operational models to determine the best fit for CDCR facilities.
- Each model was evaluated against pre-established criteria, including:
  - Type and level of care required at each facility, i.e., reception center and licensed beds,
  - Impact on patient clinical outcomes.
  - Regulatory requirements.
  - STAT testing access.
- The following three models did not meet CDCR laboratory or health care strategic needs considering the current state of laboratory operations. However, one (or a combination) of these models may play a role in future CDCR laboratory operations, but only after a robust, basic laboratory infrastructure exists.

Model	Pros	Cons
Full Outsourcing to a reference laboratory	Turn key solution	Reference lab control
	Easy implementation	Risk of poor service
	Short timeline	Higher Cost
University Hospital Relationship	High quality	Information technology
		Courier services
		Stat Services
Independent Hospital Relationship	Stat services	Limited esoteric menu
		Information technology

## Future State – Preferred Operational Models

- NCI performed an in-depth evaluation of the following three operational models, with CPR's Steering Committee found most feasible in meeting CDCR strategic needs.

<b>Model A</b>	Maintain laboratories at <i>'pre-qualified'</i> CDCR facilities; reference services rendered by a commercial laboratory.
<b>Model B</b>	Establish one 'State-wide' laboratory with several regional 'hubs supporting CDCR facilities in their corresponding region.
<b>Model C</b>	Establish only regional 'hubs' (potentially three) to support CDCR facilities in their corresponding region.

**The CPR Steering Committee considers Model B a better fit to support the future needs of the CDCR population and overall long-term health care delivery system**

# Future State – Preferred Operational Models > Service Delivery

			MODELS		
How are the following services handled?			A	B	C
		Stat testing	POCT; RRL; Local Hospital, Reference Lab	POCT; Hub/Main Lab; Local Hospital; Reference Lab	POCT; Hubs; Local Hospital; Reference Lab
		Routine testing	Reference Lab	CDCR state-wide lab	CDCR Hubs and Reference Lab
		Esoteric testing	Reference Lab	CDCR state-wide lab and Reference Lab	Reference Lab
	Histology and Cytology		Reference Lab	Reference Lab	Reference Lab
		Courier	Reference Lab	Reference Lab; Internal	Reference Lab; Internal
	Physician access to orders		Browser-based	Browser-based	Browser-based
	Physician access to test results		Browser-based	Browser-based	Browser-based
	Connectivity to EMR		Interface	Interface	Interface
		POCT testing	Level I - II	Level I - II	Level I - II
		POCT connectivity	Interface/middleware	Interface/middleware	Interface/middleware
		Test tracking	LIS	LIS	LIS
		Bar-code labels	At point of test order	At point of test order	At point of test order
	Medical directorship		CDCR contracted	CDCR contracted	CDCR contracted

# Future State – Preferred Operational Models > Performance Criteria

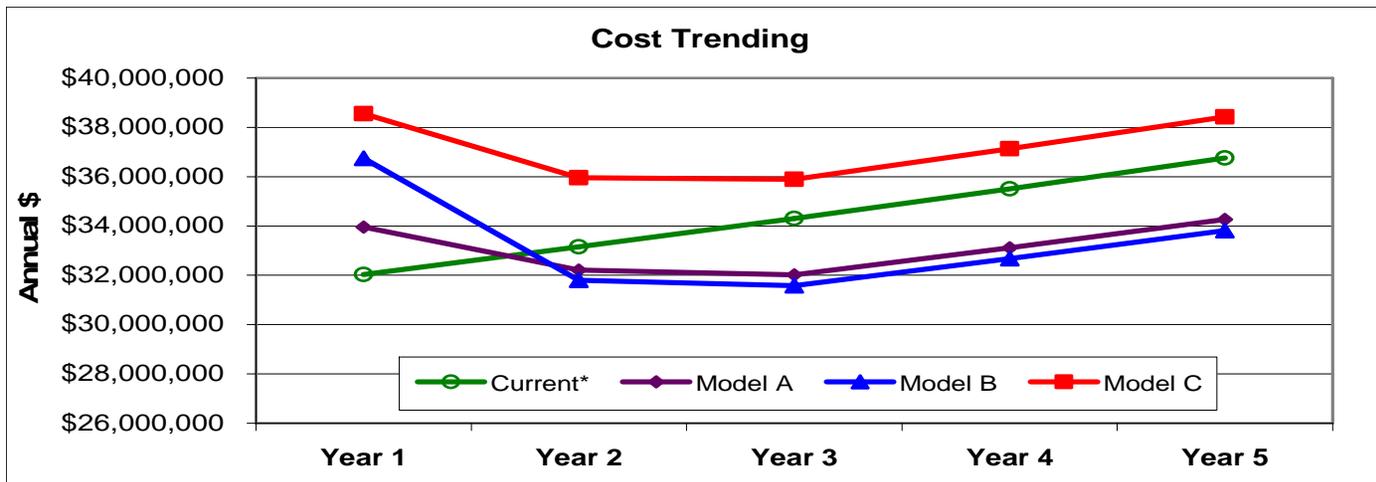
PERFORMANCE CRITERIA	Model 'A'	Model 'B'	Model 'C'
Oversight and management	★	★	★
Internal governance	★	★	★
Quality management program	★	★	★
Personnel management	★	★	★
Medical Directorship	★	★	★
Information systems	★	★	★
Electronic order, tracking and reporting at multiple point of services	★	★	★
Interface to EMR	★	★	★
Universal access to laboratory records	★	★	★
Standardized laboratory test menu	★	★	★
Consistence of testing across sites	★	★	★
Access to routine and esoteric testing	★	★	★
Point of Care Testing support and oversight	★	★	★
Logistics Support	★	★	★
STAT Laboratory Network	★	★	★
Courier Services Network	★	★	★
Quality and Service Standards	★	★	★
Standardized test codes and reference ranges	★	★	★
24 hours routine TAT testing	★	★	★
2-4 hours STAT TAT	★	★	★

All models meet the basic performance criteria highlighted in green.  
 All models present a (manageable) level of dependency on outside providers (yellow).

# Future State – Preferred Operational Models > Costs

Model Cost Comparison					
Options	Year 1	Year 2	Year 3	Year 4	Year 5
	\$	\$	\$	\$	\$
<b>Current*</b>	\$ 32,028,972	\$ 33,149,986	\$ 34,310,235	\$ 35,511,094	\$ 36,753,982
<b>Model A</b>	\$ 33,950,440	\$ 32,209,807	\$ 32,012,600	\$ 33,122,541	\$ 34,271,330
<b>Model B</b>	\$ 36,742,202	\$ 31,792,455	\$ 31,580,641	\$ 32,675,463	\$ 33,808,604
<b>Model C</b>	\$ 38,554,473	\$ 35,955,506	\$ 35,889,398	\$ 37,135,027	\$ 38,424,253

\* Current costs are estimated due to the lack of reliable data available.



## Future State – Preferred Operational Models > Savings Projections

### Projected Five-Year Savings

Model	Five-Year Cumulative Cost	Five-Year Cumulative Savings
Baseline	\$171,754,268	\$ -
A	\$165,566,719	\$6,187,549
B	\$166,599,364	\$5,154,904
C	\$185,958,657	(\$14,204,389)

## Future State – Laboratory Model A Definition

- In this model a limited number of CDCR facilities retain in-house laboratories based on pre-qualification criteria.
- **Facility ‘Qualification’ Criteria:**
  - 1) Hospital and/or RRL proximity to support STAT services.
  - 2) Acute Care Hospital, CTC, TTA on-site.
- A reference laboratory partner will provide routine, esoteric and pathology services to all facilities in the system.
- A robust POCT program will complement all operations.
- Under this model, the following facilities would qualify for various levels of testing:

Laboratory Level	# of Qualifying Facilities
Level I	9
Level II	22
Level III	3

## Future State – Laboratory Model A Definition > Pros and Cons

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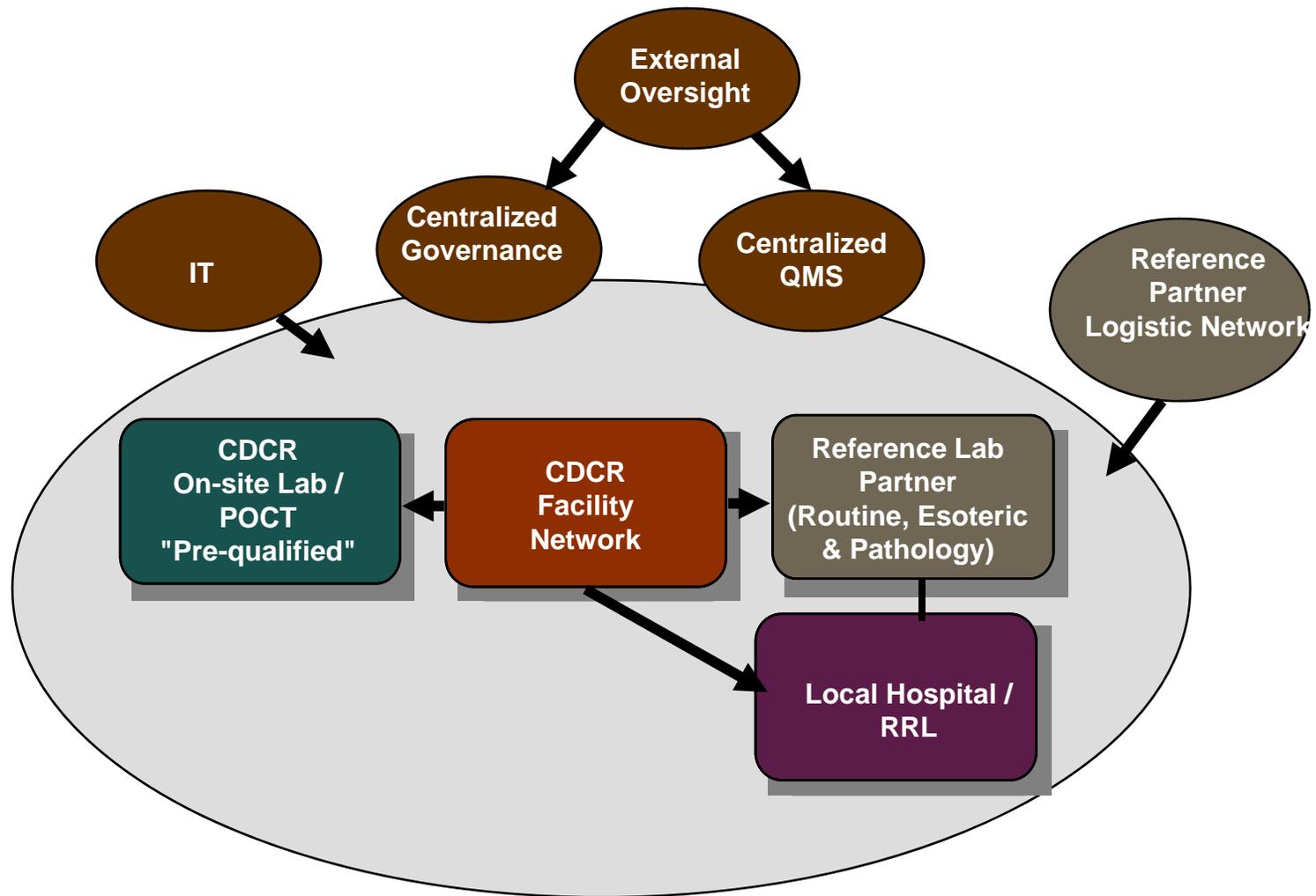
### Pros

- Centralized management for all system functions
- System-wide quality management
- More autonomy for some facilities
- Utilization of current technical personnel at selected sites
- Timeline for implementation 12 months
- Access to STAT laboratory services

### Cons

- Personnel recruiting challenges
- Space constraints within the prison walls
- Variability of application of established standards
- Availability and training of nursing personnel for support of enhanced POCT (Level II)
- Long-term sustainability
- Dependency on reference laboratory vendor

# Future State – Laboratory Model A Definition > Logistics



## Future State – Laboratory Model A Definition > Costs

Model "A" Costs					
	Year 1	Year 2	Year 3	Year 4	Year 5
<b>Centralized Management</b>					
Consulting Fees	\$ 1,830,000	\$ 1,830,000	\$ -	\$ -	\$ -
Medical Directorship (Contracted)	\$ 300,000	\$ 300,000	\$ 300,000	\$ 300,000	\$ 300,000
Central Management Team Wages and Benefits	\$ -	\$ -	\$ 580,000	\$ 600,300	\$ 621,311
<b>Total Central Management</b>	<b>\$ 2,130,000</b>	<b>\$ 2,130,000</b>	<b>\$ 880,000</b>	<b>\$ 900,300</b>	<b>\$ 921,311</b>
<b>Laboratory Operational Expenses</b>					
Labor Wages and Benefits	\$ 8,856,715	\$ 9,166,701	\$ 9,487,535	\$ 9,819,599	\$ 10,163,285
Supplies	\$ 3,271,813	\$ 3,386,326	\$ 3,504,848	\$ 3,627,517	\$ 3,754,481
<i>Total Onsite Laboratory expenses</i>	\$ 12,128,528	\$ 12,553,027	\$ 12,992,383	\$ 13,447,116	\$ 13,917,765
Reference Labs	\$ 16,437,900	\$ 17,013,226	\$ 17,608,689	\$ 18,224,993	\$ 18,862,868
Information Technology	\$ 496,188	\$ 513,554	\$ 531,528	\$ 550,132	\$ 569,387
<b>Total Laboratory Operational Expenses</b>	<b>\$ 29,062,615</b>	<b>\$ 30,079,807</b>	<b>\$ 31,132,600</b>	<b>\$ 32,222,241</b>	<b>\$ 33,350,020</b>
<b>Capital Expenditures</b>	<b>\$ 2,757,825</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>
<b>Total Cash Flow</b>	<b>\$ 33,950,440</b>	<b>\$ 32,209,807</b>	<b>\$ 32,012,600</b>	<b>\$ 33,122,541</b>	<b>\$ 34,271,330</b>

## Future State – Laboratory Model B Definition

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- In this model CDCR will operate a State-wide Laboratory with optional lab hubs and pre-qualified RRL on site. The model will include:
  - One Core laboratory, strategically located to support all routine testing including high complexity tests.
    - Core laboratory acts as centralized hub for all administrative, technical, operational, regulatory and client support functions.
    - Optional lab hubs will serve multiple prisons in close proximity.
    - ‘Hubs’ will provide a combination of phlebotomy, rapid response services and specimen consolidation hubs.
    - On-site testing POCT; on-site RRL based on pre-qualification criteria.
    - Partnership with reference laboratory for the provision of esoteric testing, Anatomical Pathology services, and logistic support.
    - Alternatively logistic support may be provided by CDCR.
    - STAT services handled by a combination of POCT, testing hubs, regional lab, and contracted providers.

## Future State – Laboratory Model B Definition > Pros and Cons

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### Pros

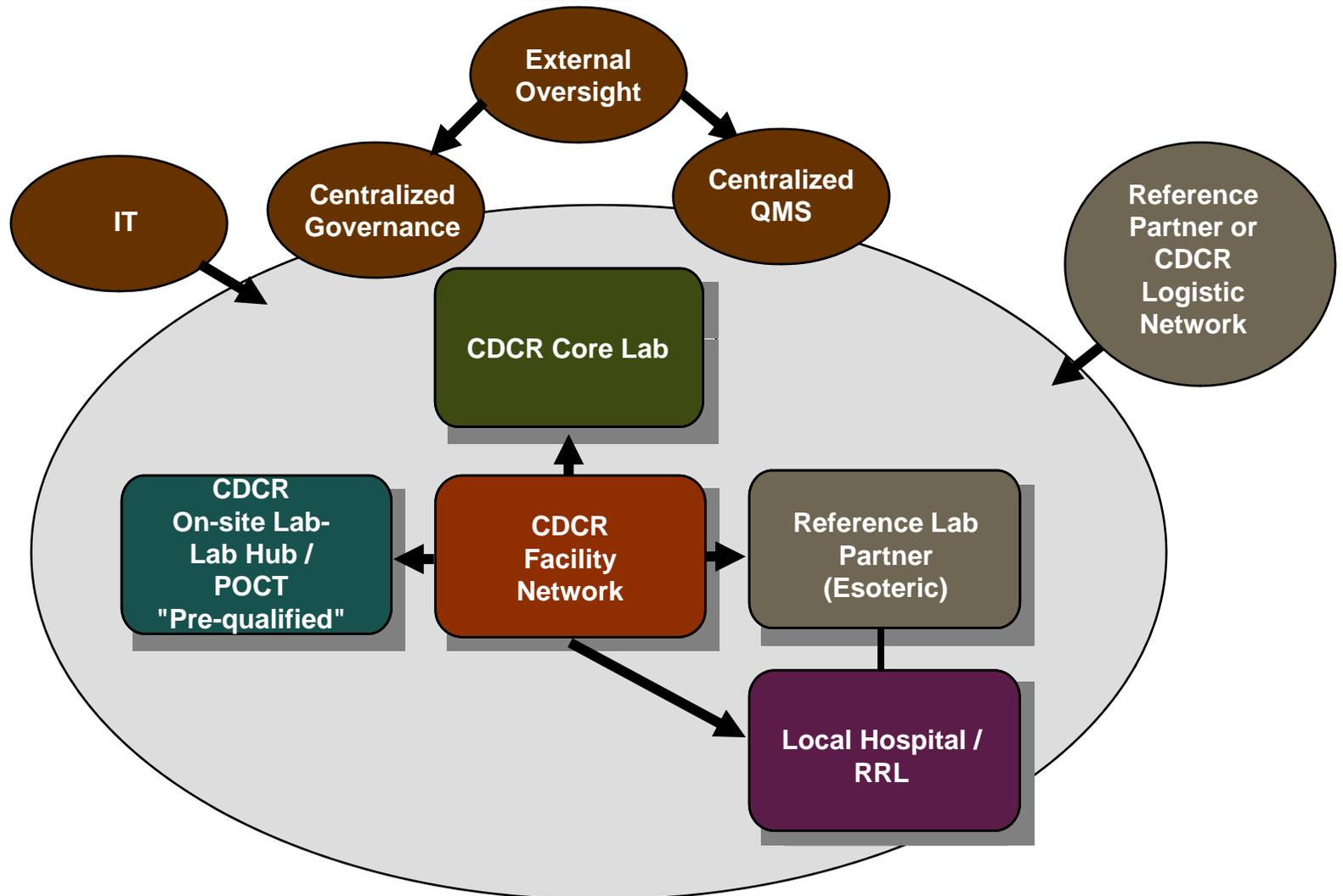
- Centralized management for all system functions
- System-wide quality management
- Ability to attract high caliber technical personnel
- Analytical consistency
- Utilization of current technical personnel at selected sites
- Built-in redundancy
- Sustainable
- Cost effective
- Optimal access to rapid response services

### Cons

- Build vs. buy decision for multiple sites
- Recruitment of capable leadership
- Timeline for implementation 24-36 months
- Availability and training of nursing personnel for support of enhanced POCT (Level II)

**Model B is considered the most feasible model of this evaluation. However, the laboratory enterprise should be stabilized first, followed by a re-validation of the feasibility of this model, prior to implementation.**

# Future State – Laboratory Model B Definition > Logistics



# Future State – Laboratory Model B Definition > Costs

Model "B" Costs					
	Year 1	Year 2	Year 3	Year 4	Year 5
<b>Centralized Management</b>					
Consulting Fees	\$ 1,830,000	\$ 1,830,000	\$ -	\$ -	\$ -
Medical Directorship (Contracted)	300,000	300,000	300,000	300,000	300,000
Central Management Team Wages and Benefits	-	-	580,000	600,300	621,311
<b>Total Central Management</b>	<b>\$ 2,130,000</b>	<b>\$ 2,130,000</b>	<b>\$ 880,000</b>	<b>\$ 900,300</b>	<b>\$ 921,311</b>
<b>Laboratory Operational Expenses</b>					
Labor Wages and Benefits	\$ 17,456,872	\$ 18,067,862	\$ 18,700,237	\$ 19,354,746	\$ 20,032,162
Supplies	\$ 6,957,594	\$ 7,201,110	\$ 7,453,149	\$ 7,714,009	\$ 7,983,999
Core Lab Lease	\$ 375,000	\$ 388,125	\$ 401,709	\$ 415,769	\$ 430,321
Core Lab Utilities and Other Costs	\$ 150,000	\$ 155,250	\$ 160,684	\$ 166,308	\$ 172,128
Logistics	\$ 240,000	\$ 248,400	\$ 257,094	\$ 266,092	\$ 275,406
<i>Total Onsite Laboratory expenses</i>	\$ 25,179,466	\$ 26,060,747	\$ 26,972,873	\$ 27,916,924	\$ 28,894,016
Reference Labs	\$ 2,925,223	\$ 3,027,606	\$ 3,133,572	\$ 3,243,247	\$ 3,356,761
Information Technology	\$ 554,688	\$ 574,102	\$ 594,195	\$ 614,992	\$ 636,517
<b>Total Laboratory Operational Expenses</b>	<b>\$ 28,659,377</b>	<b>\$ 29,662,455</b>	<b>\$ 30,700,641</b>	<b>\$ 31,775,163</b>	<b>\$ 32,887,294</b>
<b>Capital Expenditures</b>	<b>\$ 5,952,825</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Total Cash Flow</b>	<b>\$ 36,742,202</b>	<b>\$ 31,792,455</b>	<b>\$ 31,580,641</b>	<b>\$ 32,675,463</b>	<b>\$ 33,808,604</b>

## Future State – Laboratory Model C Definition

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- Under this model CDCR will operate a network of ‘hubs’ - a Rapid Response Laboratory Network.
  - Several strategically located regional hubs to support all STAT and routine high volume tests for prisons in close proximity.
    - ‘Hubs’ will provide a combination of phlebotomy, rapid response services and specimen consolidation.
  - Centralized management and oversight for all administrative, technical, operational, regulatory, client and logistic support functions.
  - On-site testing will be limited to POCT basic or enhanced.
  - Partnership with reference laboratory for the provision of esoteric testing and anatomical pathology services.
  - STAT services handled by a combination of POCT, testing hubs, and contracted providers.
  - Logistic support may be provided by CDCR or purchased from reference laboratory partner.

## Future State – Laboratory Model C Definition > Pros and Cons

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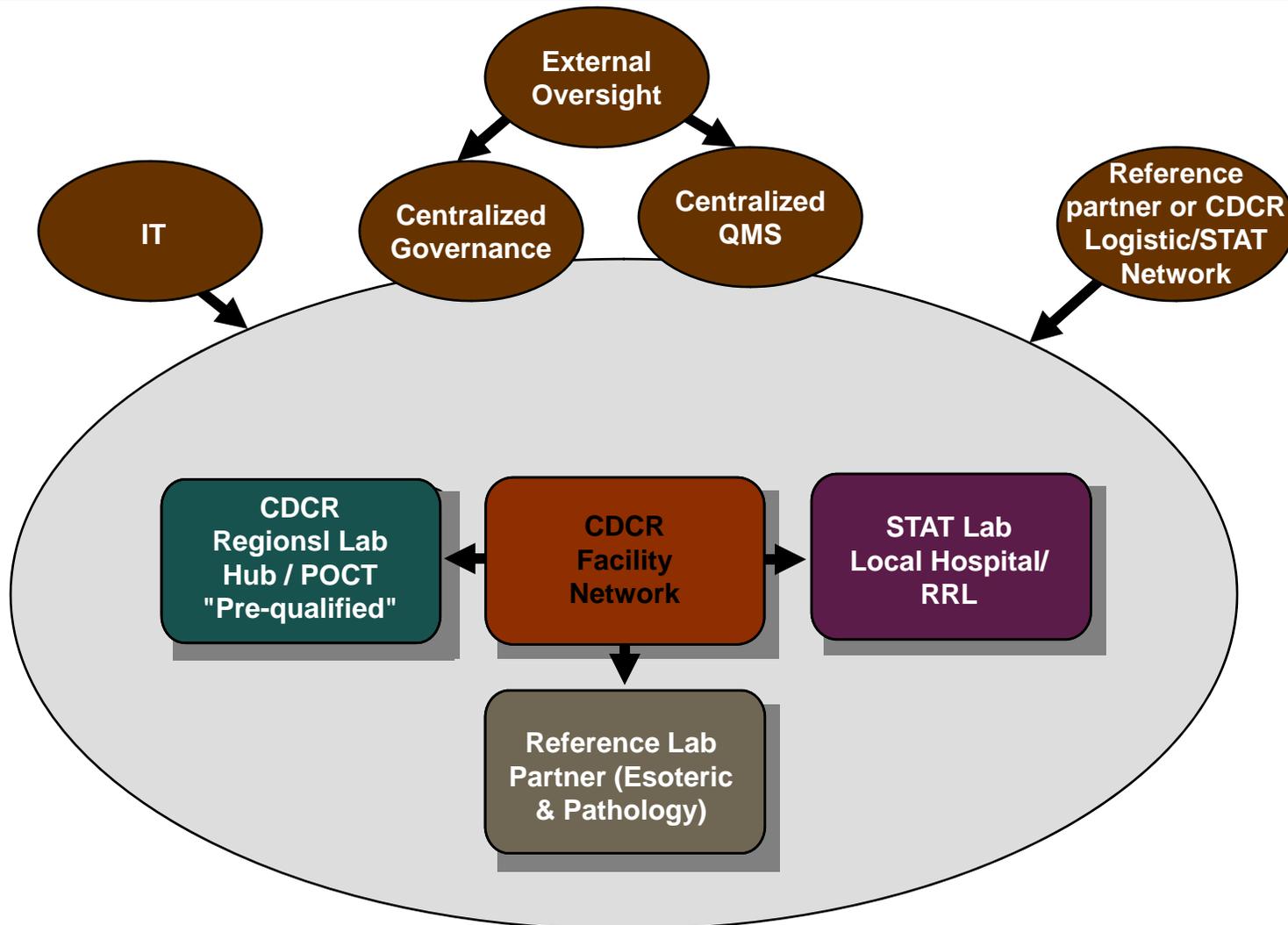
### Pros

- Centralized management for all system functions
- System-wide quality management
- Utilization of current technical personnel at selected sites
- Built-in redundancy
- Access to rapid response services

### Cons

- Site selection; build vs. buy
- Recruitment of capable leadership and personnel
- Establishment of logistics network
- Timeline for implementation 24-36 months
- Dependency on reference laboratory
- Duplication of efforts and consistency of testing throughout the system
- Availability and training of nursing personnel for support of enhanced POCT (Level II)

# Future State – Laboratory Model C Definition > Logistics



# Future State – Laboratory Model C Definition > Costs

Model "C" Costs					
	Year 1	Year 2	Year 3	Year 4	Year 5
<b>Centralized Management</b>					
Consulting Fees	\$ 1,830,000	\$ 1,830,000	\$ -	\$ -	\$ -
Medical Directorship (Contracted)	\$ 300,000	\$ 300,000	\$ 300,000	\$ 300,000	\$ 300,000
Central Management Team Wages and Benefits	\$ -	\$ -	\$ 580,000	\$ 600,300	\$ 621,311
<b>Total Central Management</b>	<b>\$ 2,130,000</b>	<b>\$ 2,130,000</b>	<b>\$ 880,000</b>	<b>\$ 900,300</b>	<b>\$ 921,311</b>
<b>Laboratory Operational Expenses</b>					
Labor Wages and Benefits	\$ 12,631,277	\$ 13,073,371	\$ 13,530,939	\$ 14,004,522	\$ 14,494,680
Supplies	\$ 3,822,868	\$ 3,956,668	\$ 4,095,152	\$ 4,238,482	\$ 4,386,829
Core Lab Lease	\$ 300,000	\$ 310,500	\$ 321,368	\$ 332,615	\$ 344,257
Core Lab Utilities and Other Costs	\$ 120,000	\$ 124,200	\$ 128,547	\$ 133,046	\$ 137,703
Logistics	\$ 772,200	\$ 799,227	\$ 827,200	\$ 856,152	\$ 886,117
<i>Total Onsite Laboratory expenses</i>	\$ 17,646,344	\$ 18,263,966	\$ 18,903,205	\$ 19,564,817	\$ 20,249,586
Reference Labs	\$ 14,626,116	\$ 15,138,030	\$ 15,667,861	\$ 16,216,236	\$ 16,783,805
Information Technology	\$ 409,188	\$ 423,509	\$ 438,332	\$ 453,673	\$ 469,552
<b>Total Laboratory Operational Expenses</b>	<b>\$ 32,681,648</b>	<b>\$ 33,825,506</b>	<b>\$ 35,009,398</b>	<b>\$ 36,234,727</b>	<b>\$ 37,502,943</b>
<b>Capital Expenditures</b>	<b>\$ 3,742,825</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>
<b>Total Cash Flow</b>	<b>\$ 38,554,473</b>	<b>\$ 35,955,506</b>	<b>\$ 35,889,398</b>	<b>\$ 37,135,027</b>	<b>\$ 38,424,253</b>

## Section V – Financial Analysis

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- Capital and Start-up Assumptions
  - Financial Pro-forma
  - Cost Trending
  - Savings
- Preferred Operational Models – Staffing
- Preferred Operational Models – Test Volumes
- Information Systems

## Financial Analysis – Capital/Start-up Assumptions

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- New operational model implementation requires external oversight from a professional healthcare management organization in year-one and year-two.
  - Cost \$1.83 million per year
- Transition to self-management will occur in year-three, the senior management team will include:
  - Executive Director -\$150,000
  - Laboratory Technical Manager-\$100,000
  - Senior Clinical Laboratory Scientist (2)-\$75,000 each
- Baseline salaries were adjusted to competitive market rates for all technical positions.
- Employee Benefits are estimated at 45% of salaries.
- POCT testing expenses for the baseline and models represent a best estimate and only include costs for glucose monitoring under the following assumptions:
  - Five percent diabetes incidence in a prison population of 160,000 inmates.
  - 8,000 prisoners requiring one test per day.
  - Over 2 million tests required at a total cost of \$1.4M.

# Financial Analysis – Capital/Start-up Assumptions

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- Staffing for the operational models was calculated using standard productivity standards.
  - Core Laboratory 0.13 WMH/test
  - Rapid Response Labs 0.21 WMH/test
- Laboratory expenses include a 3.5% inflation increase each of the five years, per year.
- Information Technology Capital and Support expenses:
  - Capital expense \$1.3 M in year-one.
  - One-time LAN drop expense \$57,200 in year-one (22 facilities @\$2,600 per facility).
  - Annual Information system maintenance fees \$409,000 per year; Years one - five.
    - *30% of original capital investment a year .*

# Financial Analysis – Capital/Start-up Assumptions

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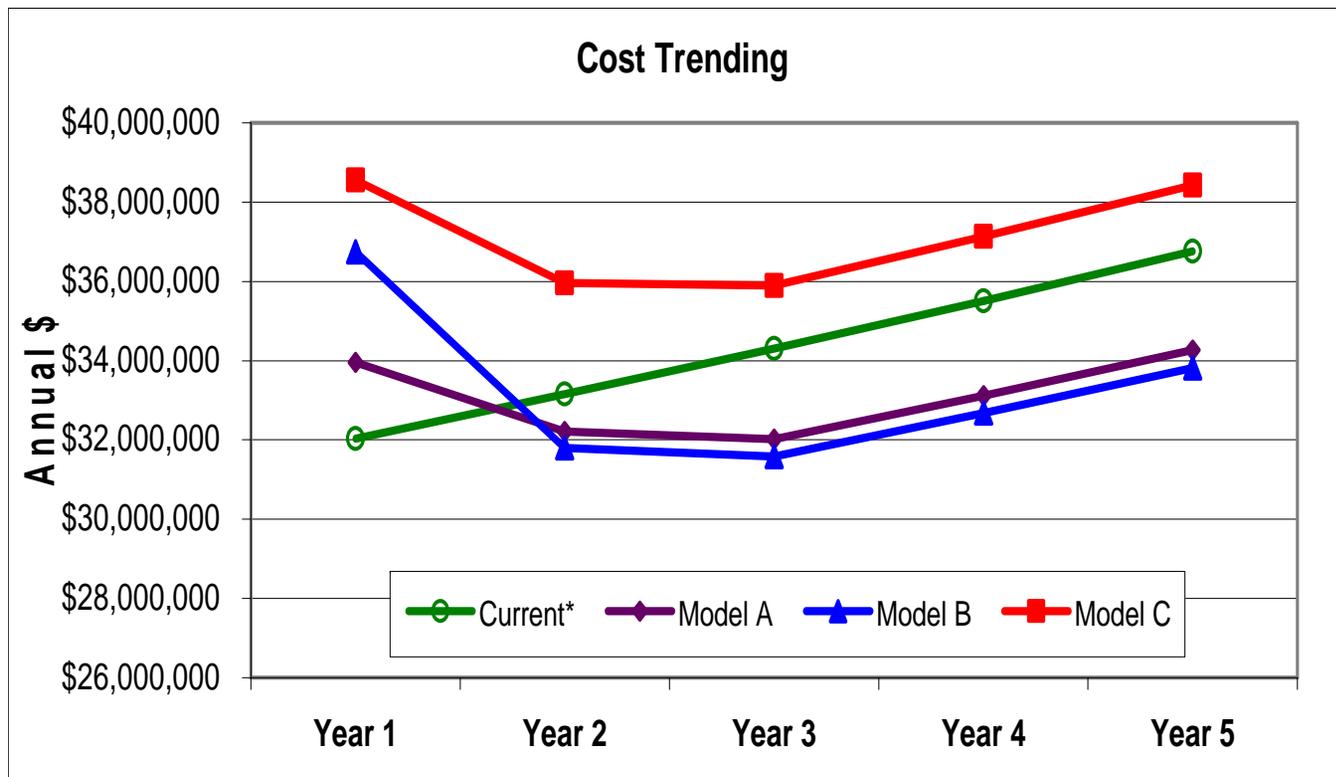
- Site Development Capital Investment:
  - Model A - space remodeling \$1.13 M.
    - *Three RRLs requiring 1,500 SQF each within prison wall.*
    - *Remodeling cost /SQF @ \$250*
  - Model B - core laboratory with three laboratory hubs capital investment \$5.4 M.
    - *15,000 SQF core laboratory @ \$200 SQF.*
    - *12,000 SQF for three hubs with 4,000 SQF each @ \$200 SQF .*
  - Model C - capital investment \$2.4 M.
    - *12,000 SQF for three hubs with 4,000 SQF each @ \$200 SQF.*
- Total Capital expenses for each preferred model:
  - Model A - \$2.4 M
  - Model B - \$6.7 M
  - Model C - \$3.7 M

## Financial Analysis – Capital/Start-up Assumptions > Financial Pro-forma

Model Cost Comparison						
Options	Year 1	Year 2	Year 3	Year 4	Year 5	
	\$	\$	\$	\$	\$	\$
<b>Current*</b>	\$ 32,028,972	\$ 33,149,986	\$ 34,310,235	\$ 35,511,094	\$ 36,753,982	
<b>Model A</b>	\$ 33,950,440	\$ 32,209,807	\$ 32,012,600	\$ 33,122,541	\$ 34,271,330	
<b>Model B</b>	\$ 36,742,202	\$ 31,792,455	\$ 31,580,641	\$ 32,675,463	\$ 33,808,604	
<b>Model C</b>	\$ 38,554,473	\$ 35,955,506	\$ 35,889,398	\$ 37,135,027	\$ 38,424,253	

**\* Current costs are estimated due to the lack of reliable data available.**

# Financial Analysis – Capital/Start-up Assumptions > Cost Trending



## Financial Analysis – Capital/Start-up Assumptions > Savings

Model	Five-Year Cumulative Cost	Five-Year Cumulative Savings
Baseline	\$171,754,268	\$ -
A	\$165,566,719	\$6,187,549
B	\$166,599,364	\$5,154,904
C	\$185,958,657	(\$14,204,389)

The savings presented under each model DO NOT reflect potential additional savings (+/-15%) over five years made possible with overall system overhaul

## Financial Analysis – Preferred Operational Models > Staffing

FTE Impact	Model A	Model B	Model B <sub>1</sub>	Model C	Baseline
Supervisor SCLT	3	11	17	9	4
SCLT	22	22	14	14	21
CLT	19	59	70	46	26
Lab Assistant	72	105	89	74	118
<b>Total</b>	<b>116</b>	<b>197</b>	<b>190</b>	<b>143</b>	<b>169</b>
<b>FTE change from the baseline</b>	<b>-53</b>	<b>28</b>	<b>21</b>	<b>-26</b>	

\* B1 reflects a slight difference in staffing between having a RRL Vs hubs

**FTE reductions in the various models may be achieved through discontinuance of agency personnel, vacant positions, and attrition.**

## Financial Analysis – Preferred Operational Models > Test Volumes

Test Volumes	Model A	Model B	Model C	Current
In House Testing	458,519	2,275,809	1,464,959	578,528
Reference Tests	2,092,916	252,868	1,063,718	1,950,149
% of tests performed in house	18%	90%	58%	23%

# Financial Analysis – Laboratory Information Systems

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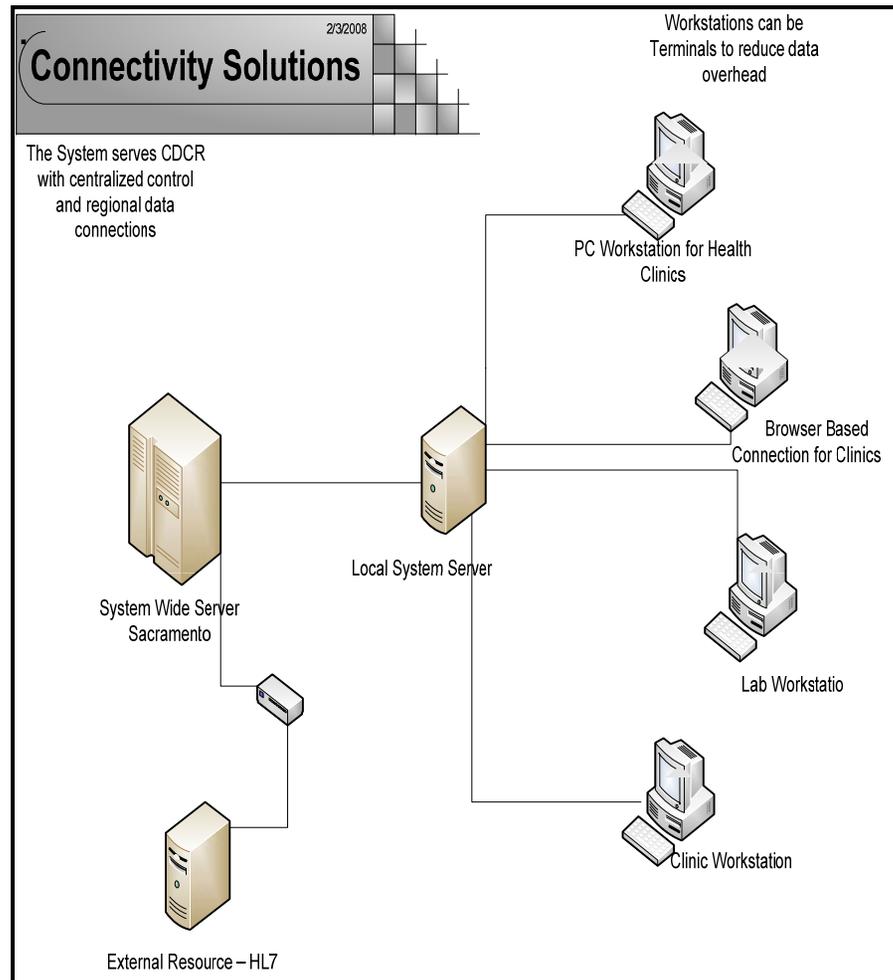
- CDCR laboratories will implement the required Laboratory Information System(s) (LIS) geared to improving patient safety and privacy, while providing clinicians with seamless access to test results (from in-house laboratories, POCT, reference laboratory providers) to assist in clinical diagnosis and disease management of inmates.
- The LIS will provide the required features to help prison clinics conform to HIPAA security and privacy standards.
- The LIS will provide a system-wide solution with connectivity to all locations, driven from a central site, with HL7 interfacing to health care facilities and reference laboratories.
- The LIS will have advanced rules-based functionality to allow automation of manual tasks (currently in existence at CDCR) to begin at the point where orders are created.
  - Decision support rules will direct test orders and specimens to the corresponding testing site, e.g. CDCR in-house laboratories, CDCR testing hubs, reference laboratories, state laboratories, and POCT devices.
- The LIS, through its order entry functions, will create high resolution bar-code labels; specimens directed to testing sites will be 100% pre bar-coded and will include the required patient identifiers to secure positive inmate identification.

# Financial Analysis – Future State of Laboratory Information Systems

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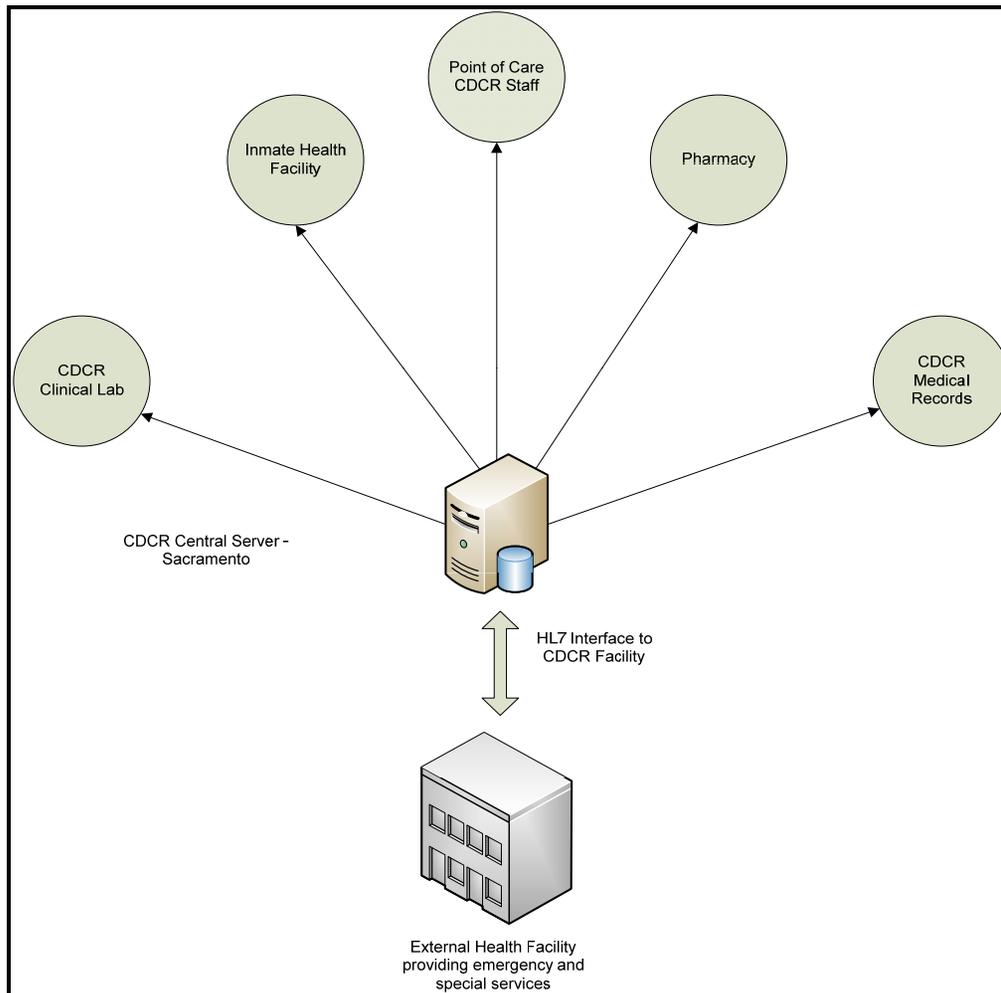
- The LIS will accept middleware interfacing to process test results from POCT devices and display the same in as part of the electronic medical record.
- The LIS will contain the required modules to support CDCR-based laboratory services as well as hub-based laboratory services in all laboratory specialties.
- The LIS will provide a dashboard of work flow, specimen and result tracking, turnaround monitoring, and other (LIS) standard features to oversee laboratory services from multiple locations.
- The LIS will have available the necessary remote site/WAN capabilities for result ordering tests and reviewing patient test results via high-speed connections.
- The LIS will meet the necessary CDCR requirements for result dissemination upon the validation and release of test results. The system will create reports in a comprehensive format that is clear and meets all regulatory requirements.
- The LIS will provide the ability to interface to multiple third-party software vendors, support bi-directional interfacing to various laboratory analyzers, reference laboratory vendors, electronic medical records, hospital information systems, CDCR practice and other information systems.

# Financial Analysis – Future State of Laboratory Information Systems



- This visual is only intended to highlight centralized Information System capabilities and possible data connections.
- The final LIS/IT architectural design will be driven by the final model selected, number of sites with laboratory operations, laboratory instrumentation inventory, and overall CDRC IT system design.

# Financial Analysis – Future State of Laboratory Information Systems



- This visual is only intended to highlight the seamless data exchange and capabilities throughout the laboratory and clinics.
- The final IT architectural design will be driven by the final model selected, number of sites with laboratory operations, laboratory instrumentation inventory, and overall CDRC IT system design.

## Section VI – Exhibits

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- I. CDCR Facility Interviews
- II. CDCR Laboratory System Resources
- III. CDCR Laboratory Information Systems
- IV. Correctional Facility Models In Other US States
- V. Reference Laboratory Capabilities For Partnership
- VI. Reference Laboratories – Unmet Obligations
- VII. Reference Laboratories – Quality And Accuracy
- VIII. Reference Laboratories – Billing Practices
- IX. Job Description (Proposed) – Certified Phlebotomy Technician
- X. Job Description (Proposed) – Senior Clinical Laboratory Scientist
- XI. Job Description (Proposed) – Clinical Laboratory Scientist
- XII. Regulatory Requirements For Acute Licensed Bed Facilities
- XIII. Hospital Facility Proximity (To Prisons)
- XIV. CDCR Inter-laboratory Facility Proximities
- XV. Courier Service Feasibility
- XVI. Summary of Quality Concerns

# Exhibit I – CDCR Facility Interviews

Name	Title	Facility
Erica Weinstein, MD	Health Care Manager	Avenal State Prison (ASP)
Ellen Greenman, MD	Chief Medical Officer	Avenal State Prison (ASP)
Pat Acala	Senior Clinical Laboratory Scientist	Avenal State Prison (ASP)
Dr. Adye	Chief Surgeon	Avenal State Prison (ASP)
Julie Duke	Medical Records	Avenal State Prison (ASP)
Christine Cahoun	Office Assistant	Avenal State Prison (ASP)
Glen Bowder	Correctional Health Services Administrator I	CA Correctional Center (CCC)
Gina Donaldson	Laboratory Assistant	CA Correctional Center (CCC)
Dr. Andrew Pmazel	Health Care Manager, Chief Medical Officer	CA Correctional Center (CCC)
Larry Maldonado	Healthcare Administrator	CA Institution for Men (CIM)
Dr. Muhammae Farooq	Chief Medical Officer	CA Institution for Men (CIM)
Dr. John Hiserodt	Laboratory Medical Director	CA Institution for Men (CIM)
Kamel G. Sadek	Senior Clinical Laboratory Scientist	CA Institution for Men (CIM)
Dr. Hannah	Chief Psychiatrist	CA Institution for Men (CIM)
Honey Shew	Senior Laboratory Assistant	CA Institution for Men (CIM)
Cynthia Myers	Laboratory Assistant	CA Institution for Men (CIM)
Steven Shively	Correctional Health Services Administrator II	CA Institution for Women (CIW)
Jackqueline Long, MD, MBA, FACOG	Health Care Manager, Chief Medical Officer	CA Institution for Women (CIW)
Johnny Amcheta	Clinical Laboratory Scientist	CA Institution for Women (CIW)
Susie Biancsi	Laboratory Assistant/Phlebotomist	CA Institution for Women (CIW)
Paul Torres	Laboratory Assistant/Phlebotomist	CA Institution for Women (CIW)
Robert Meyers, MD	Health Care Manager, Chief Medical Officer	CA Men's Colony (CMC)
Steven Herrera	Senior Clinical Laboratory Scientist, SBB	CA Men's Colony (CMC)

# Exhibit I – CDCR Facility Interviews

Name	Title	Facility
Cathy Gizler	Correctional Health Services Administrator I	CA Men's Colony (CMC)
Sarv Grover, MD	Health Care Manager, Chief Medical Officer	CA Rehabilitation Center (CRC)
Carol Ellsworth	Correctional Health Services Administrator I	CA Rehabilitation Center (CRC)
Pat Viste	Senior Clinical Laboratory Scientist	CA Rehabilitation Center (CRC)
Vickie Yamamoto	Healthcare Manager	CA State Prison, Corcoran (COR)
Agnes Y. Wu, MD	Laboratory Director	CA State Prison, Corcoran (COR)
Maria George	Senior Clinical Laboratory Scientist	CA State Prison, Corcoran (COR)
Andre McGarrell	Senior Clinical Laboratory Scientist	CA State Prison, Corcoran (COR)
Mathew Chapman	Laboratory Assistant	CA State Prison, Corcoran (COR)
Derrick Musgrove	Senior Clinical Laboratory Scientist	CA State Prison, Sacramento (SAC)
Gail Martinez	Health Care Manager	CA Substance Abuse Treatment Facility (SATF)
Thomas Volk, MD	Laboratory Director	CA Substance Abuse Treatment Facility (SATF)
Alice Roque	Laboratory Supervisor	CA Substance Abuse Treatment Facility (SATF)
Martin Levin	Health Care Manager	Calipatria State Prison (CAL)
Linda Gilstrap	Medical Secretary	Calipatria State Prison (CAL)
Nasaria Barreras	Chief Medical Officer	Centinela State Prison (CEN)
R Davis	Health Care Manager	Centinela State Prison (CEN)
Angelina Ariola	Laboratory Assistant	Centinela State Prison (CEN)
Sampath Suryadevara, MD	Health Care Manager, Chief Medical Officer	Central CA Women's Facility (CCWF)
Deborah Lee	Compliance Coordinator	Central CA Women's Facility (CCWF)
John Culton, MD	Health Care Manager, Chief Medical Officer	Chuckawalla Valley State Prison (CVSP)
Rosario Ignacio	Senior Clinical Laboratory Scientist	Chuckawalla Valley State Prison (CVSP)
Josheph Chudy	Health Care Manager, Chief Medical Officer	Correctional Training Facility (CTF)
Robert Corridos	Senior Clinical Laboratory Scientist	Correctional Training Facility (CTF)
Paramvir Sahota, MD	Health Care Manager	Folsom State Prison (FOL)
Teresa Cameron	Senior Laboratory Assistant	Folsom State Prison (FOL)
Ray Masbad	Administrator I	Folsom State Prison (FOL)
Norma Aquaviva	Health Care Manager	High Desert State Prison (HDSP)
Pam Philiips	Laboratory Assistant	High Desert State Prison (HDSP)
Georgia Joshua	Correctional Health Services Administrator, Laboratory Supervisor	High Desert State Prison (HDSP)
John Stiles, MD	Health Care Manager, Chief Medical Officer	Ironwood State Prison (ISP)

# Exhibit I – CDCR Facility Interviews

Name	Title	Facility
Lina Dominguez	Clinical Laboratory Scientist	Ironwood State Prison (ISP)
Sharon Zamora	Health Care Manager	Kern Valley State Prison (KVSP)
Shery Lopez, MD	Chief Medical Officer	Kern Valley State Prison (KVSP)
Thomas Volk, MD	Lab Director	Kern Valley State Prison (KVSP)
Marilou Riola	Senior Clinical Laboratory Scientist	Kern Valley State Prison (KVSP)
Brett Williams, MD	Health Care Manager	Mule Creek State Prison (MCSP)
Laura Medina	Compliance Coordinator	Mule Creek State Prison (MCSP)
Ann Hudson	Laboratory Assistant	Mule Creek State Prison (MCSP)
Jose Ayson, MD	Health Care Manager, Chief Medical Officer & Lab Director	North Kern State Prison (NKSP)
Sylvia Lowvorn	Correctional Health Services Administrator II	North Kern State Prison (NKSP)
Dr. Thomas Volt	Consulting Pathologist	North Kern State Prison (NKSP)
Pete Riola	Laboratory Supervisor	North Kern State Prison (NKSP)
Carol Ellsworth	Correctional Health Services Administrator II	Pelican Bay State Prison (PBSP)
Pat Viste	Senior Clinical Laboratory Scientist	Pelican Bay State Prison (PBSP)
William Alvarez, PhD	Health Care Manager	Pleasant Valley State Prison (PVSP)
Felix Igbinoso, MD	Chief Medical Officer	Pleasant Valley State Prison (PVSP)
Cecilia Samareta	Clinical Laboratory Scientist	Pleasant Valley State Prison (PVSP)
John Webster	Correctional Health Services Administrator II	R.J. Donovan Correctional Facility at Rock Mountain (RJD)
Elizabeth Romero, MD	Chief Medical Officer	R.J. Donovan Correctional Facility at Rock Mountain (RJD)
Lela Gaumbatta	Laboratory Supervisor	R.J. Donovan Correctional Facility at Rock Mountain (RJD)
Rosalva Gonzalez	Medical Secretary	R.J. Donovan Correctional Facility at Rock Mountain (RJD)
Charles Dudley Lee, MD	Health Care Manager, Chief Medical Officer	Salinas Valley State Prison (SVSP)
John Chu	Senior Clinical Laboratory Scientist	Salinas Valley State Prison (SVSP)
Cecilia Galermo	Senior Laboratory Assistant	Salinas Valley State Prison (SVSP)
Rene Tejada	Senior Clinical Laboratory Scientist	San Quentin State Prison (SQ)
Troy Brimhall	Health Care Manager	Sierra Conservation Center (SCC)
Curtus Allen, MD	Chief Physician Surgeon	Sierra Conservation Center (SCC)
Christina Levisque	Senior Clinical Laboratory Scientist	Sierra Conservation Center (SCC)
Daun Martin, PhD	Health Care Manager	Valley State Prison for Women (VSPW)
Pal Virk, MD	Chief Medical Officer	Valley State Prison for Women (VSPW)
Corryn Pierini	Correctional Health Services Administrator I	Valley State Prison for Women (VSPW)
Frances Aragon	Laboratory Assistant	Valley State Prison for Women (VSPW)

# Exhibit I – CDCR Facility Interviews

Name	Title	Facility
Antoinette Gaines	Laboratory Assistant	Valley State Prison for Women (VSPW)
Omar Sinza	Laboratory Assistant (agency)	Valley State Prison for Women (VSPW)
Dr. Michael Songer	Health Care Manager	Wasco State Prison (WSP)
Rosemary Linear	Laboratory Assistant	Wasco State Prison (WSP)
Aida Aposta	Clinical Laboratory Scientist	Wasco State Prison (WSP)
Nelson Nisperos	Clinical Laboratory Scientist	Wasco State Prison (WSP)
Maria Banertee	Senior Clinical Laboratory Scientist	Wasco State Prison (WSP)
Diana Alvarez	HIM	Wasco State Prison (WSP)
Beverly Bemis	Clinical Laboratory Scientist	California Correctional Institution
Joan Tracy	Health Care Manager (A)	California Correctional Institution
Timothy Pruitt	Health Care Manager	California Medical Facility
George Pounds	Laboratory Manager (Acting)	California Medical Facility
Dr. Snell	Health Care Manager	Deuel Vocational Institution
Lisa Cardwell	FNP that oversees the laboratory	Deuel Vocational Institution
Cynthia Frederick	CHSA I	Deuel Vocational Institution

## Exhibit II – CDCR Laboratory System Resources

LABORATORY TEST PERFORMANCE					
	In House Testing			Reference Laboratories	
	In House Laboratory	In House Testing	POCT	Foundation	Quest
Number of Facilities	11	9	23	22	11
Annualized Test Volumes				1'141,408	476,656
Annualized Cost				\$ 10,982,346.00	\$ 4,095,924.00
CLIA LICENSE					
	None	Waived	Moderate Complexity	High Complexity	
Number of Facilities	8	14	6	5	
PERSONNEL					
Information Source	SCLS	CLS	Sr. Lab Assistant	Lab Assistant/ Phlebotomist	Lab Assistant/ Phlebotomist (Agency)
Interview Finding	25.00	26.50	3.00	51.00	63.60
Sacramento	25.00	19.00	2.00	52.00	n/a
LABORATORY EQUIPMENT					
Number of Analyzers	Siemens	Coulter	Abbott	J & J	Other
Chemistry	9			3	1
Hematology	2	3	4		
Urinalysis					4
STAT LABORATORY SERVICES					
	within 5 miles	within 10 miles	within 20 miles	Greater than 20 miles	Greater than 50 miles
Hospital Lab	11 facilities	9 facilities	6 facilities	4 facilities	1*

## Exhibit III – CDCR Laboratory Information Systems

LIS Key Features	Skylab	Fletcher-Flora	Genesis	Med-Com	Gem	CSS
Electronic Order entry	Y	Y	Y	Y	Y	Y
Track complete sample-results data	Y	Y	Y	Y	Y	Y
Control and record completed test data (Including QC)	N	N	N	N	N	N
Provide clinic base result information	N	N	N	N	N	N
Accumulate results to historical data base	Y	Y	Y	Y	Y	Y
Bar code labels for sample tubes	Y/N	N	N	N	N	Y
Interface to Laboratory equipment	Y	Y	N	N	N	Y
Direct interface to reference laboratory	N	N	N	N	N	N
Ability to create special reports for trending results across time	N	N	N	N	N	Y
monitoring therapies based on laboratory results	N	N	N	N	N	N

## Exhibit IV – Correctional Facility Models in Other US States

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- NCI interviewed correctional facility representatives from Texas, New York, Florida, and Nevada to identify best laboratory models and practices in other states.
- The major findings of this research suggest that the methods of laboratory health care delivery vary significantly from state to state; facilities **do not** operate in-house laboratories; weaknesses in STAT handling exist throughout; and the use of POCT has not been used to capacity.

The common trends identified include:

- Prisons do not operate ‘in-house’ laboratories, except one facility in FL operating a hospital.
- Prisons use mainly commercial laboratory relationships for most of their laboratory services.
- Most prisons find it challenging to manage STAT requests; both commercial laboratories and local hospital relationships exist to support these services.
- Most prisons offer only waived POCT, e.g. glucose monitoring; hesitation exists to expand their POCT program due to compliance-related concerns.
- Several state prisons do not monitor laboratory costs. Texas tracks their cost on a PMPM basis, while Florida tracks costs on per encounter basis. Costs vary significantly based inmate segregation (e.g. infectious disease facilities) and reception centers.
- Prisons lack Information Systems – Texas is the only facility with some level of sophistication and interfacing of laboratory data to their EMR system.

# Exhibit IV – Correctional Facility Models in Other US States

		CORRECTIONAL FACILITY LOCATIONS ....			
Summary of research findings					
		TEXAS	FLORIDA	NEVADA	NEW YORK
1	Do prisons operate ' in-house' laboratories?	No	** Only one of 4 regions	No	No
2	Do prisons offer basic POCT (e.g. glucose monitoring)?	Yes	Yes	Yes	Yes
3	*****How are STAT services handled?	Ref. lab and local hospital arrangement			
4	Are test orders entered manually or electronically?	*** Hooked to EMR	Manual	Manual	Manual
5	Are test results available electronically?	Hooked to EMR	LabCorp browser-based	Manual	Manual
6	Internal/External laboratory oversight?	Internal	Internal	Internal	Internal
7	What is the laboratory cost/inmate?	**** \$1 - \$6 PMPM	***** \$11.54 per encounter	NA	NA
8	Reference laboratory provider?	* LabCorp and UTMB hospital	LabCorp	LabCorp	LabCorp/local hospital at some sites
*	TX - services are rendered by the UTMB hospital facility covering a 500-mile radius; LabCorp supports remote facilities.				
**	FL - only Region II has an in-house hospital, which also supports lab services facilities within that region.				
***	TX - most test results available on-line, although there are deficiencies with the Order Entry interfaces.				
****	TX - reception center facilities cost up to \$6 PMPM vs medical facilities.				
*****	FL - average cost per encounter is approximately \$11.54; the system produces over 3M encounters/Yr.				
*****	All facilities experience similar challenges, particularly with STAT service logistics and turn around time.				

## Exhibit V – Reference Laboratory Capabilities For Partnership

Reference Laboratory Evaluation and Scoring					
Criteria	Quest	Foundation	LabCorp	University*	Network **
<b>Enterprise Management and support</b>					
Laboratory testing system management	2	1	2	1	1
Personnel Management	2	1	2	1	1
Medical Directorship	3	1	3	2	2
<b>Information Technology</b>					
Electronic order, tracking and reporting at multiple point of services	3	2	3	1	1
Interface to EMR	3	2	3	1	1
Universal access to laboratory records	3	1	3	1	1
<b>Laboratory Test Menu</b>					
Esoteric Testing	3	2	3	2	2
Routine Testing	3	3	3	3	3
Point of Care Testing support and oversight	1	1	1	1	1
<b>Logistics Support</b>					
STAT Laboratory Network	3	2	3	1	3
Courier Services Network	3	2	3	1	2
<b>Quality and Service Standards</b>					
Standardized test codes and reference ranges	2	3	3	3	1
24 hours routine TAT testing	3	3	3	3	3
2-4 hours STAT TAT	3	2	3	1	3
Timely and effective access to Critical Values	3	3	3	3	3
Quality Management Reports	3	2	3	2	2
<b>Score</b>	<b>43</b>	<b>31</b>	<b>44</b>	<b>27</b>	<b>30</b>

\* University settings considered include UC Davis, UC Irvine, UCLA, and UCSD.

\*\* Reflects local, community hospitals considered.

**The highest score laboratories are best positioned to partner with CDCR to support laboratory services and future operations. LabCorp currently has a strong presence in Correctional Facilities in other states.**

## Exhibit V – Reference Laboratory Capabilities For Partnership

Reference Laboratory Capabilities					
Criteria	Quest	Foundation	LabCorp	University	Local Network
Number of in state Laboratory facilities	3	1	5	1	TBD
Number of state Rapid response labs	30	0	100	0	0
Number of Stat Laboratory Hospitals in network	32	3	60	TBD	TBD
Experience in prison setting	Y	Y	Y	N	N
Partnership willingness	Y	Y	Y	Y	TBD
Partnership ability	Y	N	Y	N	TBD
Turn key solution	Y	N	Y	N	N

**Reference laboratory Networks are strong throughout the state of California. A combination of Rapid Response laboratories, hubs, and hospital relationships should (if well-managed) be able to meet the STAT needs of CDCR facilities.**

# Exhibit VI – Reference laboratories > Unmet Obligations - Contractual Requirements

QUEST DIAGNOSTICS

California Department of Corrections and Rehabilitation and Rehabilitation (CDCR)

SCOPE OF WORK

Agreement Number ICM06099

Exhibit A

## STAT LABORATORY AND ROUTINE LABORATORY TESTING

### 1. INTRODUCTION/SERVICES

A. Contractor shall provide all labor, materials, equipment, staff, transportation, license, permits and every other item of expense necessary to provide **STAT Laboratory and Routine Laboratory Testing** for inmates referred for such medical services from the California Department of Corrections and Rehabilitation and Rehabilitation (CDCR).

B. Contractor shall provide clinical pathology and laboratory services to include all basic laboratory supplies, e.g., slides, vacutainers, needles meeting current California Occupational Safety and Health Administration (CAL OSHA) requirements, tubes, sterile containers, laboratory report forms and labels for processing STAT and routine laboratory tests and for processing microscopic and gross tissue examinations.

C. Contractor shall supply all packaging materials, including but not limited to, labels for handling biological/pathological materials including STAT labels, report forms, and other materials deemed necessary for transport by the Contractor.

# Exhibit VI – Reference laboratories > Unmet Obligations - Contractual Requirements

QUEST DIAGNOSTICS

California Department of Corrections and Rehabilitation and Rehabilitation (CDCR)

SCOPE OF WORK

Agreement Number ICM06099

Exhibit A

### 3. CONTRACTOR PROVIDED SERVICES AND EQUIPMENT

F. Contractor shall provide courier service for pick up of Level 2 and 3 samples, specimen(s), and tissues as described herein in paragraph entitled "LEVELS OF LABORATORY TESTS", Monday through Friday at a mutually agreed upon time by the HCM/CMO and Contractor. Courier service shall be available twenty-four (24) hours a day, seven (7) days a week, including holidays, for Level 1 (STAT) samples, specimens, or tissues. The location for all pick up and/or delivery of all samples will be at the gate or visitor locations of the Institution or at a location specified by the HCM/CMO.

G. Contractor shall provide STAT testing twenty-four (24) hours a day, seven (7) days a week, including holidays. Contractors who do not have facilities available within the immediate area of the Institution shall provide written proof of other alternative agreement/arrangement with a local laboratory or hospital facility for STAT testing. No additional reimbursement will be made for STAT testing.

# Exhibit VI – Reference laboratories > Unmet Obligations - Contractual Requirements

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QUEST DIAGNOSTICS

California Department of Corrections and Rehabilitation and Rehabilitation (CDCR)

Agreement Number ICM06099

Exhibit A

## 5. LEVELS OF LABORATORY TESTS

A. There are three (3) levels of criticality of samples, specimens and/or tissues to be received from CDCR. These levels apply to services performed by the Contractor for the Institution. The amount of time allowed for initiating an analysis depends on the level of criticality.

Level 1. STAT Analysis or testing of any sample, specimen, or tissue labeled "STAT" must begin immediately upon arrival at the laboratory. STAT orders shall be

## Exhibit VII – Reference Laboratories > Quality and Accuracy

- The current reference laboratory arrangements consistently fail to meet CDCR laboratory needs

	Quest	Foundation	Examples
Inaccurate test results		X	Male wound culture reported as normal vaginal flora
TAT failures		X	Soft tissue biopsy delay
Inadequate access to STAT laboratory services	X	X	System wide
CLIA Compliance	X		Medical Director
Questionable billing practices		X	Billing for indices

## Exhibit VII – Reference Laboratories > Quality and Accuracy Pathology Turnaround Time

---

**From:** Levin, M.D., Martin

**Sent:** Tue 1/15/2008 12:13 PM

**To:** Winslow, Dwight; Ritter, Steven D.O.; Bruns, Mary Jo

**Subject:** Foundation Lab

I know many of us in the field have complained about the Foundation Lab in the past. Again they have shown their inefficiency and why they need to be replaced. A soft tissue biopsy of a tongue that I did last week will not be ready for another week. They tell my lab person that all soft tissue biopsies take two weeks. The only reason this would take this long is that they do not have pathologists to read specimens and send them out, which means they are not a full service laboratory to begin with. A soft tissue biopsy should be read in 48-72 hours unless it can not be ID'd and has to be sent to AFIP. Fortunately for this patient, I am anticipating the tissue will be benign.





# Exhibit VII – Reference Laboratories > Quality and Accuracy Chemistry Results / Original



**FOUNDATION  
LABORATORY**

M.Y. Nestr, M.D., Director  
Allon Jay M.D., Co-Director and Pathologist

R. J. DONOVAN CORRECTIONAL FAC-1  
480 ALTA RD.  
HOSPITAL/Cont# RJD03010  
SAN DIEGO, CA 92179

PATIENT NAME
--------------

AGE	DOB	SEX	ID NO	ACCESSION NO.
35		M	F59203	1629824

DRAWN DATE	DRAWN TIME	RECEIVED DATE	RECEIVED TIME
11/13/07	7:30	11/13/07	23:00

PHYSICIAN
ARMSTRONG, - MD (RJD)

REPORT DATE	REPORT TIME
11/14/07	11:11

STATUS	PAGE
FINAL	1

RESULT

TEST	OUT OF RANGE	IN RANGE	UNITS	REFERENCE RANGE
------	--------------	----------	-------	-----------------

CTC 182

SPECIAL CHEMISTRY				
AMMONIA	311.0 H		umol/L	16.0-60.0

# Exhibit VII – Reference Laboratories > Quality and Accuracy Chemistry Results

## SHARP CHULA VISTA MEDICAL

Sharp HealthCare  
751 Medical Center Court  
Chula Vista, CA 91911-  
(619) 482-3619

Director of Pathology:  
Cameron K. Campbell M.D.

CC:

Patient:  
SHC#: 0104408845  
EMRN: (00006)00481881  
Admit#: 60517018 Ptype: X  
DOB: M - 35 YRS  
Phone#: / -

Admit Dr: FOUNDATION LABORATORY

## CHEMISTRY

<u>COLLECTION</u> DATE	<u>TIME</u>	<u>RESULT</u>	<u>REF RANGE</u>
11/14/07	1505	92	(9-33)
		AMMONIA (umol/L)	

# Exhibit VII – Reference Laboratories > Quality and Accuracy Chemistry Results



**FOUNDATION LABORATORY**  
M.Y. Nasir, M.D., Director  
Allen Jay M.D., Co-Director and Pathologist

R. J. DONOVAN CORRECTIONAL FAC-1  
480 ALTA RD.  
HOSPITAL/Cont# RJD03010  
SAN DIEGO, CA 92179

PATIENT NAME				AGE	SEX	ID NO.	ACCESSION NO
				35	M	F59203	1638038
DRAWN DATE	DRAWN TIME	RECEIVED DATE	RECEIVED TIME	PHYSICIAN			
11/19/07	7:30	11/19/07	23:00	ARMSTRONG, MD (RJD)			
REPORT DATE	REPORT TIME	RESULT		STATUS		PAGE	
11/20/07	14:53			FINAL		1	
TEST	OUT OF RANGE	IN RANGE	UNITS	REFERENCE RANGE			
CTC 182							
SPECIAL CHEMISTRY							
AMMONIA		359.0 H	umol/L	16.0-60.0			

**SHARP CHULA VISTA MEDICAL**  
Sharp HealthCare  
751 Medical Center Court  
Chula Vista, CA 91911-  
(619) 482-3619

Director of Pathology:  
Cameron K. Campbell M.D.

CC:

patient:  
SIC#: 0104408845  
EMRN: (00006)00481881  
Admit#: 60517018 Ptype: X  
DOB: M - 35 YRS  
Phone#:

Admit Dr: FOUNDATION LABORATORY

### CHEMISTRY

COLLECTION DATE	TIME	RESULT	REF RANGE
12/03/07	1515	96 *	(9-33)
11/21/07	1200	77 *	(9-33)
11/18/07	0820	89 *	(9-33)
11/16/07	1946	107 *	(9-33)
11/14/07	1505	92 *	(9-33)

*Grossly elevated NH<sub>3</sub> on Foundation Labs with much lower values on followup at Sharp C.V.*

# Exhibit VII – Reference Laboratories > Quality and Accuracy Platelets



Foundation Laboratory  
1716 W. Holt Ave.  
Pomona, CA 91768  
Ph (909) 623 9301  
Fax (909) 623 9306

Client:  
R.J. DONOVAN CORRECTIONAL FAC-1  
480 ALTA RD.  
HOSPITAL/Cont# RJD03010  
SAN DIEGO, CA 92179

Patient Name: )

LYLE, MD (RJD)  
Patient I.D. F62019 Date of Birth Age: 43 Sex: M  
Accession: 1638191  
Collected: 11/19/07 10:20 Date: Time: Status: FINAL  
Received: 11/19/07 23:00  
Reported: 11/20/07 14:53

Test	Normal	Abnormal	Units	Reference
364-110 FAXED @ 8:49 11/20/2007 JANE				
<b>HEMATOLOGY</b>				
WBC	5.5		10 <sup>3</sup> /uL	4.2-10.5
HgB	14.7	3.96 L	10 <sup>6</sup> /uL g/dL	4.6-6.2 14-18
HCT	43.8			42-52
MCV		110.7 H	um <sup>3</sup>	80-94
MCH		37.2 H	pg	27-34
MCHC	33.6			31.5-36.0
RDW	11.6			11-14.8
<b>PLATELETS</b>		<b>10 CL</b>	<b>10<sup>3</sup>/uL</b>	<b>150-400</b>
VERIFIED BY REPEATED ANALYSIS				
MPV	8.6		cu/mm	6.8-10.6
GRANULOCYTES %	66.6			48.9-69.9
GRANULOCYTES#	3.64		10 <sup>3</sup> /uL	1.5-6.7
LYMPHOCYTES %	26.5			22.4-43.6
LYMPHOCYTES#		1.45 L	10 <sup>3</sup> /uL	1.5-4.0
MONOCYTES %		4.4 L		6.2-9.8
MONOCYTES#	0.24		10 <sup>3</sup> /uL	0.2-0.8
EOSINOPHIL %	2.1			0-5.0
EOSINOPHIL#	0.11		10 <sup>3</sup> /uL	0-0.40
BASOPHIL %	0.4			0-2.0
BASOPHIL#	0.02		10 <sup>3</sup> /uL	0-0.20
RBC MORPHOLOGY	SeeBelow			
PLATELETS		Clumped		Normal
"Platelet clumps" may reflect the value of the platelet's result.				

# Exhibit VII – Reference Laboratories > Quality and Accuracy Platelets



Foundation Laboratory  
1716 W. Holt Ave.  
Pomona, CA 91768  
Ph (909) 623 9301  
Fax (909) 623 9308

Client:  
R.J. DONOVAN CORRECTIONAL FAC-1  
480 ALTA RD.  
HOSPITAL/Cont# RJD03010  
SAN DIEGO, CA 92179

Patient Name: ( )  
Physician: LYLE, MD (RJD)  
Patient I.D. F82019      Date of Birth      Age: 43      Sex: M  
Accession: 1640790      Other ID:  
  
Collected: 11/20/07 15:10      Status: FINAL  
Received: 11/20/07 23:44  
Reported: 11/21/07 9:04

Test	Normal	Abnormal	Units	Reference
3GYM 110 STAT FAXED @ 0:21 11-21-07 JCB. NON-FASTING HEMATOLOGY PLATELETS	269		10 <sup>3</sup> /uL	150-400

# Exhibit VIII – Reference Laboratories > Billing Practices Foundation Billing

LATARA ENTERPRISE, DBA FOUNDATION LABORATORY  
1716 W. HOLT AVE  
POMONA, CA 91768  
PHONE (909) 623-9301 FAX (909) 623-9306

CSP-CORCORAN  
4001 KING AVE  
CORCORAN, CA 93212  
CONTRACT # COR03023

1176

Invoice number: 14878  
Statement Date: 10/01/2007  
Due Date: 11/01/2007

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DATE	ACCN NO.	PATIENT	PROCEDURE	FEE
			83894 SEPARATION-PC	1.34
9/21/2007	1561272	NAME	82607 VITAMIN B12	7.26
9/21/2007	1561273	NAME	87070 WOUND CULTURE	2.48
			87088 ORGANISM ISO	6.40
			87186 MIC-AMPICILLIN	103.32
			87181 SENSY-AMPICIL/	6.50
9/21/2007		NAME	87070 WOUND CULTURE	2.48
			87088 ORGANISM ISO	3.25
			87186 MIC-AMPICILLIN	63.14
			87181 SENSY-AMPICIL/	6.87
7/16/2007		NAME		0.00
			DOS 7/16/07	0.00
			85025 CBC-HOSPITAL	44.90
			DOS 7/23/07	0.00
			80076 LIVER-HOSPITAL	123.65
			80048 BMP-HOSPITAL	121.90
			85025 CBC-HOSPITAL	44.90
		NAME		0.00
			DOS 7/03/07	0.00
			80076 LIVER-HOSPITAL	123.65
			80048 BMP-HOSPITAL	121.90
			85025 CBC-HOSPITAL	44.90
		NAME		0.00
			DOS 7/17/07	0.00
			85610 PT-HOSPITAL	46.00
			85730 PTT-HOSPITAL	46.00

**Sample Invoice:**  
  
**High cost of hospital lab work rendered under the Foundation Lab arrangement**

# Exhibit VIII – Reference Laboratories > Billing Practices Foundation Billing

<u>Date</u>	<u>Accession</u>	<u>Patient</u>	<u>CPT</u>	<u>Test Description</u>	<u>Fee</u>
4/19/2007	1360170		99001	HANDLING S/O	\$ -
			99001	HANDLING S/O	\$ 2.99
			99001	HANDLING S/O	\$ 2.99
			99001	HANDLING S/O	\$ 2.99
			99001	HANDLING S/O	\$ 2.99
3/27/2007	1330245		80076	LIVER PANEL	3.38
			80092	HYPOTHYROID P	11.15
			80053	COMP METABOLI	5.57
			85025	CBC-PENTRA	3.98
			85007	MANUAL DIFF	1.19
			84100	PHOSPHORUS	1.99
			82465	CHOLESTEROL,	1.59
			84478	TRIGLYCERIDES	2.19
			83615	LDH,SERUM	2.99
			84550	URIC ACID, SE	2.19
			82977	GGT,SERUM	2.99
3/29/2007	1333146		80074	HEPATITIS PAN	28.91
			86708	HAV A AB TOTA	8.56
			86706	HBsAb	6.79
			86704	HBc TOTAL	8.85

# Exhibit IX – Proposed Job Description > Certified Phlebotomist

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- Position: Certified Phlebotomy Technician
- Department: Clinical Laboratory
- Reports to: Senior Clinical Laboratory Scientist/Clinical Laboratory Scientist
- Category: Non-Exempt
- Created on: February 28, 2008
- Pay Grade:
- **Position Summary:**
- The Certified Phlebotomy Technician collects, handles and processes laboratory specimens under the direction of the Senior Clinical Laboratory Scientist and Clinical Laboratory Scientist.
- **Job Duties:**
- Receive laboratory orders and generate specimen collection schedule
- Collect blood specimens using proper vein-puncture technique.
- Transport and receive laboratory specimens to be processed.
- Accession laboratory specimens in the LIS.
- Process laboratory specimens for testing (centrifugation; aliquoting; etc)
- Accession and process reference laboratory specimens.
- Evaluate specimen integrity and identification, takes corrective action as necessary to ensure specimen quality.
- Communicate to appropriate personnel any issues related to the collection, handling and processing of specimens.
- Serve as the laboratory client support liaison, attend phones and direct issues to appropriate personnel.
- Ensure that laboratory test specimens are collected and timely in accordance with test priority.
- Identify problems that may adversely affect test performance or reporting of test results and implements corrective action or notify Clinical Laboratory Scientist.
- Maintain records in accordance with policies and procedures.
- Maintain strict patient confidentiality.
- Participate in Continuing Education activities to keep abreast of current technology and to meet State Certification requirements.
- **Skills and Attributes:**
- Communicate information and ideas verbally and in writing clearly and professionally.
- Exercise independent judgment and Decision Making-Considering all problems alternatives to choose the most appropriate one.
- Act calm under pressure and is able to prioritize and perform multiple tasks simultaneously.
- **Requirements:**
- High school graduate or have achieved a passing score on the general educational development(GED) test. Certified as a Phlebotomy Technician I in the State of California. A minimum of 6 month experience in a hospital, independent clinical laboratory or Physician office lab performing phlebotomy and laboratory assistant duties.
- **Work Environment:**
- Exposure to hazardous chemicals and infectious agents is a job risk. Must be able to stand for long periods of time and walk long distances. Prolonged times at a computer may lead to eye strain and fatigue. Standard laboratory safety regulations must be maintained to avoid contamination or injury to yourself or others.

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*Note: original document will be included as an attachment in final report*

# Exhibit X – Proposed Job Description > Senior Clinical Laboratory Scientist

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- Position: Senior Clinical Laboratory Scientist
- Department: Clinical Laboratory
- Reports to: Laboratory Medical Director
- Category: Exempt
- Created on: February 28, 2008
- Pay Grade:
- **Position Summary:**
- The Senior Clinical Laboratory/Supervisor maintains the laboratory department under the direction of the laboratory director and is directly involved in training lab personnel, developmental work on new tests, CQI activities, continuing education, maintenance of compliance for regulatory agencies, personnel scheduling, personnel performance evaluation, and, where required, performs laboratory test procedures.
- **Job Duties:**
- Oversee day-to-day laboratory operation and personnel performing testing and reporting test results.
- Monitor test performance and specimen integrity to ensure accurate test results.
- Write laboratory policies and procedures for test performance and quality system.
- Evaluate laboratory technology and make appropriate recommendations for equipment selection.
- Establish and monitor compliance with quality control requirements.
- Ensure documentation of quality control performance and remedial actions taken whenever test systems deviate from established specifications.
- Ensure that laboratory test results are reported accurately and timely in accordance with test priority.
- Identify problems that may adversely affect test performance or reporting of test results and implements corrective action or notify laboratory director.
- Train, mentor, and evaluate laboratory staff to ensure quality control, safety, and records maintenance.
- Schedule laboratory personnel and ensures proper staffing to meet service demands.
- Routinely and proactively interact with clinical personnel including physicians to ensure that services provided meet patients' needs.
- Annually evaluate and document the performance of all testing personnel.
- Maintain strict patient confidentiality.
- Participate in Continuing Education activities to keep abreast of current technology and to meet State Licensure requirements.
- **Skills and Attributes:**
- Lead through empowerment and provide an environment for personal and professional growth.
- Manage processes through workflow streamlining and proper technology implementation
- Communicate information and ideas verbally and in writing clearly and professionally.
- Exercise independent judgment and Decision Making-Considering all problems alternatives to choose the most appropriate one.
- Act calm under pressure and is able to prioritize and perform multiple tasks simultaneously.
- **Requirements:**
- A bachelor's degree in a scientific discipline, or medical technology. Licensed as a Clinical Scientist in the State of California to perform all required tests. A minimum of 2 years supervisory experience in a hospital or independent clinical laboratory.
- **Work Environment:**
- Exposure to hazardous chemicals and infectious agents is a job risk. Must be able to stand for long periods of time. Prolonged times at a computer may lead to eye strain and fatigue. Standard laboratory safety regulations must be maintained to avoid contamination or injury to yourself or others.

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*Note: original document will be included as an attachment in final report*

# Exhibit XI – Proposed Job Description > Clinical Laboratory Scientist

---

- Position: Clinical Laboratory Scientist
- Department: Clinical Laboratory
- Reports to: Senior Clinical Laboratory Scientist
- Category: Exempt
- Created on: February 28, 2008
- Pay Grade:
- **Position Summary:**
- The Clinical Laboratory Scientist processes laboratory specimens; performs laboratory testing procedures in human blood, urine, and other body fluids or tissues, using manual or automated techniques; and reports test results under the direction of the Laboratory Medical Director and Senior Clinical Laboratory Scientist.
- **Job Duties:**
- Perform all duties related to specimen handling and processing, testing, reporting of laboratory results and maintenance of records in accordance with established policies and procedures.
- Adhere to the laboratory's quality control policies; document all quality control activities, instrument and procedural calibrations and maintenance.
- Interpret and report laboratory results accurately and timely in accordance with test priority.
- Implement corrective action whenever test systems are not within the laboratory's established acceptable levels of performance.
- Identify problems that may adversely affect test performance or reporting of test results and implements corrective action or notify Senior Clinical Laboratory Scientist immediately.
- Documents all corrective actions taken when test systems deviate from the laboratory's established performance specifications.
- Perform proficiency testing and maintains records that indicate that proficiency testing samples are tested in the same manner as patient samples
- Maintain strict patient confidentiality.
- Participate in Continuing Education activities to keep abreast of current technology and to meet State Licensure requirements.
- **Skills and Attributes:**
- Communicate information and ideas verbally and in writing clearly and professionally.
- Exercise independent judgment and Decision Making-Considering all problems alternatives to choose the most appropriate one.
- Act calm under pressure and is able to prioritize and perform multiple tasks simultaneously.
- **Requirements:**
- A bachelor's degree in a scientific discipline, or medical technology. Licensed as a Clinical Scientist in the State of California to perform all required tests.
- **Work Environment:**
- Exposure to hazardous chemicals and infectious agents is a job risk. Must be able to stand for long periods of time. Prolonged times at a computer or microscope may lead to eye strain and fatigue. Standard laboratory safety regulations must be maintained to avoid contamination or injury to yourself or others.

*Note: original document will be included as an attachment in final report*

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# Exhibit XII – Regulatory Requirements for Acute Licensed Bed Facilities

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## Regulatory requirements for Laboratory Services-Correctional Treatment Centers

- *Cal. Admin. Code tit.22, s 79705*
  - *Division 5. Licensing and Certification of Health facilities*
  - *Chapter 12. Correctional Treatment Centers*
  - *Article 4. Optional Services*
  
  - *s 79705. Optional Services-Laboratory Services*
- (b) The correctional treatment center shall maintain clinical laboratory services and equipment for routine laboratory work such as urinalysis, complete blood counts, and such tests necessary to meet the needs of the correctional treatment center.
  - (c) The correctional treatment center shall maintain or make provision for clinical laboratory services for performance of tests in chemistry, microbiology, serology, hematology, pathology and blood banking.

# Exhibit XII – Regulatory Requirements for Acute Licensed Bed Facilities

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## Regulatory requirements for Laboratory Services-General Acute Care Hospitals

- *Cal. Admin. Code tit. 22, s 70243*
- *Chapter 1. General Acute Care Hospitals*
- *Article 3. Basic Services*
- *s. 70243. Clinical Laboratory Service General Requirements*
  
- (b) All hospitals shall maintain clinical laboratory services and equipment for routine laboratory work such as urinalysis, complete blood counts, blood typing, cross matching and such other tests as are required by these regulations.
  
- (c) All hospitals shall maintain or make provision for clinical laboratory services for performance of tests in chemistry, microbiology, serology, pathology and such other tests as are required by these regulations.

**CDCR should consider limiting ‘in-house’ laboratories only at facilities subjected to these regulations (based on CDCR/CPR’s legal interpretation of the same).**

## Exhibit XIII – Hospital Facility Proximities

Adult Institutions		Established Hospital Affiliation (s)	Distance to Hospital
Avenal State Prison	ASP	Coalinga Regional Medical Center Twin Cities Community Hospital	15 mi 45 mi
Calipatria State Prison	CAL	El Central Regional Hospital	25 mi
California Correctional Center	CCC	Banner Lassen Medical Center	8 mi
California Correctional Institution	CCI	Tehachapi Hospital	2.9 mi
Central California Women's Facility	CCWF	Madera Community Hospital	15 mi
Centinela State Prison	CEN	Pioneer Hospital	40 mi
California Institution for Men	CIM	Pomona Valley Medical Center	5.2 mi
California Institution for Women	CIW	Chino Community Hospital Corona Regional Medical Center	6 mi 6 mi
California Men's Colony	CMC	French Hospital Medical Center Sierra Vista Regional Medical Center	2 mi 3.3 mi
California Medical Facility	CMF	Vaca Valley Hospital	2.2 mi
California State Prison, Corcoran	COR	Corcoran District Hospital	10 mi
California Rehabilitation Center	CRC	Pomona Valley Medical Center	15 mi
Correctional Training Facility	CTF	Mee Memorial Hospital Stanford Hospital & Clinics	4 mi 4.2 mi
Chuckawalla Valley State Prison	CVSP	Palo Verde Hospital	25 mi
Deuel Vocational Institution	DVI	Sutter Tracy Community Hospital	5.2 mi
Folsom State Prison	FOL	Kindred Hospital Sacramento	< 1 mi
High Desert State Prison	HDSP	Banner Lassen Medical Center	15 mi
Ironwood State Prison	ISP	Palo Verde Hospital	18 mi
Kern Valley State Prison	KVSP	Delano Regional Medical Center	6 mi

*Note: original document will be included as an attachment in final report*

## Exhibit XIII – Hospital Facility Proximities

California State Prison, Los Angeles County	LAC	Antelope Valley Hospital	5 mi
Mule Creek State Prison	MCSP	Central Hospital	10 mi
North Kern State Prison	NKSP	Delano Regional Medical Center Mercy Hospital	2 mi 35 mi
Pelican Bay State Prison	PBSP	Sutter Coast Hospital	7 mi
Pleasant Valley State Prison	PVSP	Collinga Medical Center	6 mi
R.J. Donovan Correctional Facility at Rock Mountain	RJD	Sharp Chula Vista Medical Center	6.7 mi
California State Prison, Sacramento	SAC	Mercy Hospital of Folsom	< 1 mi
California Substance Abuse Treatment Facility	SATF	Corcoran District Hospital	10 mi
Sierra Conservation Center	SCC	Sonora Medical Center Modesto Convalescent Hospital	8.9 mi 31 mi
California State Prison, Solano	SOL	UCSF - San Francisco UCD - Davis Northbay Hospital - Vacaville Queen of the Valley - Napa Doctors' Hospital - Manteca Doctors' Hospital - Modesto	60 mi 15 mi 5 mi 18 mi 65 mi 75 mi
San Quentin State Prison	SQ	Healdsburg District Hospital	57 mi
Salinas Valley State Prison	SVSP	Salinas Valley Memorial Hospital Duram Community Hospital	30 mi 15 mi
Valley State Prison for Women	VSPW	Madeira Community Hospital	16 mi
Wasco State Prison	WSP	Delano Regional Medical Center	2.9 mi

Note:

 No established affiliation with a hospital found from interview/survey. Closest hospital denoted.

*Note: original document will be included as an attachment in final report*

# Exhibit XIV – CDCR Inter-laboratory Facility Proximity

**Legend - Facility Distance**

- Located in same city
- Less than 10 miles
- Less than 50 miles, greater than 10 miles
- Less than 100 miles, greater than 50 miles
- Less than 150 miles, greater than 100 miles

**Facility Distance Chart**

Adult Institutions	SQ	FOL	CCI	CIM	CTF	CIW	DVI	CMC	CMF	CRC	CCC	SCC	SOL	SAC	ASP	MCSP	RJD	COR	CVSP	PBSP	CCWF	WSP	CAL	LAC	NKSP	CEN	ISP	PVSP	VSPW	HDSP	SVSP	SATF	KVSP
San Quentin State Prison	SQ	103	332	429	147	435	69.5	243	48.1	438	302	128	48.1	103	216	126	509	248	609	363	158	264	578	348	269	592	609	198	158	284	147	248	269
Folsom State Prison	FOL	103	336	446	225	453	88.6	310	55.1	455	226	90.3	55.1	233	35.2	526	241	626	442	152	282	595	365	264	609	626	216	152	209	225	241	264	
California Correctional Institution	CCI	332	336	141	222	144	267	174	345	139	549	247	345	336	128	305	232	107	296	736	186	75.9	265	43.5	74.4	279	296	153	186	532	222	107	74.4
California Institution for Men	CIM	429	446	141	316	13.5	361	239	439	10.6	658	353	439	443	222	411	109	214	189	839	293	183	158	123	181	172	189	247	293	641	316	214	181
Correctional Training Facility	CTF	147	225	222	316	326	144	101	171	329	425	183	171	225	101	200	400	139	500	509	134	154	469	238	155	483	500	63.5	134	407	139	155	
California Institution for Women	CIW	435	453	144	13.5	326	370	248	448	4.1	667	362	448	452	231	420	96.7	223	184	848	302	192	153	112	190	167	184	256	302	650	325	223	190
Deuel Vocational Institution	DVI	69.5	88.6	267	361	144	370	230	82.5	376	304	58.3	82.5	88.6	154	56.7	447	186	547	485	88.4	202	516	285	200	530	547	136	88.4	287	145	186	200
California Men's Colony	CMC	243	310	174	239	101	248	230	266	250	526	235	266	311	79.9	279	321	115	424	604	174	111	393	166	125	407	424	106	174	509	101	115	125
California Medical Facility	CMF	48.1	55.1	345	439	171	448	82.5	266	451	255	129	55.7	229	74.4	522	261	622	421	166	277	591	360	278	605	622	211	166	238	171	261	278	
California Rehabilitation Center	CRC	438	455	139	10.6	329	4.1	376	250	451	670	365	451	455	233	423	99.2	225	187	851	304	194	156	107	192	170	187	259	304	653	328	225	192
California Correctional Center	CCC	302	226	549	658	425	667	304	526	255	670	329	255	223	448	256	741	454	721	347	366	497	690	580	477	704	721	431	366	17.8	425	454	477
Sierra Conservation Center	SCC	128	90.3	247	353	183	362	58.3	235	129	365	329	129	90.2	162	66.1	436	152	536	516	63.4	193	505	275	175	519	536	138	63.4	312	182	152	175
California State Prison, Solano	SOL	48.1	55.1	345	439	171	448	82.5	266	451	255	129	55.7	229	74.4	522	261	622	421	166	277	591	360	278	605	622	211	166	238	171	261	278	
California State Prison, Sacramento	SAC	103	336	443	225	452	88.6	311	55.7	455	223	90.2	55.7	233	35.2	526	241	626	442	152	282	595	365	264	609	626	216	152	209	225	216	264	
Avenal State Prison	ASP	216	233	128	222	101	231	154	79.9	229	233	162	229	233	201	201	304	43.2	404	629	102	59.6	374	143	59.7	387	404	28.3	102	431	102	43.2	59.7
Mule Creek State Prison	MCSP	126	35.2	305	411	200	420	56.7	279	74.4	423	256	66.1	74.4	35.2	201	495	210	595	461	122	250	564	334	233	578	595	184	122	239	202	210	233
R.J. Donovan Correctional Facility at Rock Mountain	RJD	509	526	232	109	400	96.7	447	321	522	99.2	741	436	522	526	304	495	296	216	921	375	265	144	205	263	116	216	329	375	723	398	296	263
California State Prison, Corcoran	COR	248	241	107	214	139	223	186	115	261	225	454	152	281	241	43.2	210	296	396	661	91.9	37.9	366	135	34.8	379	396	68.8	91.9	463	139	34.8	
Chuckawalla Valley State Prison	CVSP	609	626	296	189	500	184	547	424	622	187	721	536	622	626	404	595	216	396	1,022	475	365	97.8	263	363	103	429	475	702	499	396	363	
Pelican Bay State Prison	PBSP	363	442	736	839	509	848	485	604	421	851	347	516	421	442	629	461	921	661	1,022	552	677	991	760	664	1,005	1,022	611	552	330	509	661	664
Central California Women's Facility	CCWF	158	152	186	293	134	302	88.4	174	166	304	366	63.4	166	152	102	122	375	91.9	475	552	132	445	214	114	459	476	77.8	349	134	91.6	114	
Wasco State Prison	WSP	264	282	75.9	183	154	192	202	111	277	194	497	193	277	282	250	265	37.9	365	677	132	334	104	17.9	348	365	85.0	132	479	154	37.9	17.9	
Calipatria State Prison	CAL	578	595	265	158	469	153	516	393	591	156	690	505	591	595	374	564	144	366	97.8	991	445	334	233	399	26.9	97.8	399	445	672	468	366	399
California State Prison, Los Angeles County	LAC	348	365	43.5	123	238	112	285	166	360	107	580	275	360	365	143	334	205	135	263	760	214	104	233	102	246	263	169	214	563	238	135	102
North Kern State Prison	NKSP	269	264	74.4	181	155	190	200	125	278	192	477	175	278	264	59.7	233	263	34.8	363	664	114	17.9	399	102	347	364	85.2	114	460	155	28.4	
Centinelia State Prison	CEN	592	609	279	172	483	167	530	407	605	170	704	519	605	609	387	578	116	379	103	1,005	459	348	26.9	246	347	103	413	458	685	482	379	347
Ironwood State Prison	ISP	609	626	296	189	500	184	547	424	622	187	721	536	622	626	404	595	216	396	1,022	476	365	97.8	263	364	103	429	475	702	499	396	363	
Pleasant Valley State Prison	PVSP	198	216	153	247	83.5	256	136	106	211	259	431	138	211	216	28.3	184	329	68.8	429	611	77.8	85.0	399	169	85.2	413	429	77.8	414	84.0	68.6	85.2
Valley State Prison for Women	VSPW	158	152	186	293	134	302	88.4	174	166	304	366	63.4	166	152	102	122	375	91.9	475	552	132	445	214	114	458	475	77.8	349	134	91.6	114	
High Desert State Prison	HDSP	284	209	532	641	407	650	287	509	238	653	17.8	312	238	209	431	239	723	463	702	330	349	479	672	563	460	685	702	414	349	407	437	460
Salinas Valley State Prison	SVSP	147	225	222	316	325	145	101	171	328	425	182	171	225	102	202	398	139	499	509	134	154	468	238	155	482	499	84.0	134	407	139	155	
California Substance Abuse Treatment Facility	SATF	248	241	107	214	139	223	186	115	261	225	454	152	281	216	43.2	210	296	396	661	91.6	37.9	366	135	28.4	379	396	68.6	91.6	437	139	28.4	
Kern Valley State Prison	KVSP	269	264	74.4	181	155	190	200	125	278	192	477	175	278	264	59.7	233	263	34.8	363	664	114	17.9	399	102	347	363	85.2	114	460	155	28.4	

Distance in miles

Note: original document will be included as an attachment in final report

## Exhibit XV – Courier Service Feasibility

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- NCI conducted a high level logistical courier transportation services review to support 33 California Department of Correction facilities under various scenarios. Three laboratory hub configurations were modeled strictly from a logistical standpoint and various courier services were interviewed.

### **Parameters of Provided Courier Services:**

- Routine specimens were to arrive at the designated hub locations daily, in a timely manner to enable result generation by the following day.
- STAT courier service availability to the various hubs and contracted hospital network

### **Couriers Responsibilities:**

- Couriers to arrive at facility for pick up at designated times.
- Log specimen count and pick up times on 'Daily Manifests' for each stop.
- Daily manifest to include time of pick up, tracking number of shipment, number of pieces and weight of shipment.
- Retain hard copy of daily manifest and records.
- Specimens to arrive at appropriate laboratory hubs at the designated times.

# Exhibit XV – Courier Service Feasibility

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## Shippers Responsibilities:

- All packages for pick up and delivery to be packaged in accordance with State of California Department of Transportation (Caltran) rules and regulations, United States Department of Transportation rules and regulations (49 CFR Parts 100-185) and when applicable (air transportation required i.e. Crescent City, Susanville) International Air Transportation Associations rules and regulations (Packaging Instructions 650-Diagnostoc and Packing Instructions 602-Infectious Substance)
- Packages will be available for pickup no later than designated times.
- Packages will be available for pick up outside of security areas at each facility.

## Courier Services Interviewed:

- World Courier Ground (San Francisco, California) is a time sensitive delivery service of Pathology, Hematology and other laboratory specimens. They have fully uniformed and background checked drivers. Majority of the driver couriers are company employees. The majority of the vehicles are company owned. They are a national company. They have two depot warehouses in California. They were not in a position to supply service to many of the outlying areas that the facilities were located in i.e.: Susanville, Crescent City etc.
- Laboratory Express (Memphis, Tennessee) is a specialized courier service structured specifically for the laboratory industry. They do not depend upon other types of delivery work to support the business. They are 100% subcontracted services (1099 vendors) and have no vehicles or driver courier employees. At this time they have no service available in outlying areas.

## Exhibit XV – Courier Service Feasibility

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### Courier Services Interviewed: (cont)

- TRICOR (San Francisco, California) is a national delivery courier company headquartered in San Francisco. They have fully uniformed and background checked drivers. The driver couriers are company employees. The majority of the vehicles are company owned. They have several depot warehouse operations that are located throughout the State of California.
- They have existing courier routes in the majority of the areas the facilities are located in. They have agents in the remote facility regions i.e. Susanville, Crescent City.
- Tricor is one of the CA-based companies that could support the logistical courier needs of CDCR, including daily manifests, computer tracking of packages in route, drivers are company employees, all facility pick ups and delivery under the control of one group. Costs would vary depending on various options, but range from \$17,728 - \$20,038 per month.

**NCI validated that logistical courier services are available in the state of California to support any CDCR laboratory operational model desired, either as a stand-alone system and/or in partnership with commercial laboratory logistical services.**

# Exhibit XV – Courier Service Feasibility



*Note: original document will be included as an attachment in final report*

## Exhibit XVI – Summary of Quality Concerns

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- 48% of the CDCR facilities reported concerns with turnaround time and/or access to STAT testing and timely reporting of critical values.
  - STAT tests and critical values require immediate attention from a physician to prevent:
    - Delays on patient care
    - Misdiagnosis
    - Medication errors
    - Increase cost of care
- 21% of the CDCR facilities reported multiple incidents of questionable results, which were repeated and deemed inaccurate upon repeat. Examples cited included multiple incidents related to:
  - False positive Hepatitis C, which may lead to the implementation of inappropriate treatment, ordering of additional expensive tests and inappropriate implementation of infection control measures.
  - False elevated potassium levels. High potassium levels are associated with cardiac complications and may be life threatening.
  - Erroneous Dilantin results. Acting upon erroneous results may lead to serious side effects, including suicide and drug induced gingivitis.
  - Erroneous Hemoglobin results, which may lead to unnecessary transfusion therapy.

## Exhibit XVI – Summary of Quality Concerns

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- 94% of the CDCR facilities perform glucose monitoring testing without proper medical oversight, and do not comply with standards of practice for this type of testing.
  - Several facilities use home glucose meters to perform the testing.
  - One facility reported inmates performing their own testing.
- Accurate glucose monitor is essential to prevent serious complications of poorly managed diabetes i.e. kidney and heart problems.
- One facility reported an incident of a delayed tissue biopsy, which could have resulted in late diagnosis of a malignancy.
- In summary, it is noteworthy that these examples demonstrate the importance of physicians properly interpreting laboratory results in conjunction with clinical symptoms and patient history. In the examples cited, as is the case with most laboratory errors, the potential negative impact to the patients was mitigated by physician intervention. When a physician sees an anomalous or even abnormal laboratory result, the usual response is to repeat the test. In the cases cited the physicians acted appropriately, repeated the tests and prevented potentially adverse patient outcomes.
- NCI believes that the examples cited in this report represent ‘the tip of the iceberg’. The Clinical Laboratory Improvement Act (CLIA), the College of American Pathologists (CAP) and the Joint Commission for the Accreditation of Healthcare Organizations have established specific standards for laboratory medicine to ensure quality test results and patient safety. The current CDCR laboratory infrastructure does not meet the minimum requirements established by these agencies.